

**BEFORE THE
UNITED STATES DEPARTMENT OF
AGRICULTURE, FOOD SAFETY AND INSPECTION
SERVICE (FSIS)**

In the matter of

**BEEF AND MEAT LABELING
REQUIREMENTS: TO EXCLUDE
PRODUCTS NOT DERIVED DIRECTLY
FROM ANIMALS RAISED AND
SLAUGHTERED FROM THE DEFINITION
OF "BEEF" AND "MEAT"**

**PETITION FOR THE IMPOSITION OF BEEF AND MEAT
LABELING REQUIREMENTS: TO EXCLUDE PRODUCTS NOT
DERIVED DIRECTLY FROM ANIMALS RAISED AND
SLAUGHTERED FROM THE DEFINITION OF "BEEF" AND
"MEAT"**

Petitioner:

U.S. CATTLEMEN'S
ASSOCIATION (USCA)

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Date: February 9, 2018

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NOT DERIVED DIRECTLY FROM ANIMALS RAISED AND SLAUGHTERED
FROM THE DEFINITION OF “BEEF” AND “MEAT”**

FSIS Docket Clerk
United States Department of Agriculture
Food Safety and Inspection Service (FSIS)
Room 2534 South Building
1400 Independence Ave., SW
Washington, DC 20250-3700

Re: Petition to Establish Beef and Meat Labeling Requirements: To Exclude
Product Not Derived Directly from Animals Raised and Slaughtered from the
Definition of “Beef” and “Meat”

Dear Docket Clerk,

The U.S. Cattlemen’s Association (USCA) respectfully submits this petition requesting that the Department of Agriculture, Food Safety and Inspection Service (FSIS) establish certain beef labeling requirements. Our request is consistent with FSIS’s current policy towards the labeling of beef, but further addresses specific additional concerns.

USCA has long advocated for additional beef labeling requirements to better inform consumers. There are currently no labeling requirements applicable to products labelled as “beef” or more broadly as “meat” mandated by law.

USCA has learned that some major U.S. meatpackers and companies in other countries are heavily investing in creating alternative products that may resemble in appearance and taste beef products, including synthetic “beef” and “beef” grown in laboratories using animal cells, known as “*in vitro*” meat, “bio meat,” “clean meat,” or “cultured meat.” Such products, which are *not* derived from animals born, raised, and harvested in the traditional manner, should *not* be permitted to be marketed as “beef,” or more broadly as “meat” products.

The labels of “beef” or “meat” should inform consumers that the product is derived naturally from animals as opposed to alternative proteins such as plants and insects or artificially grown in a laboratory. Alternative products such as those described above should thus not be permitted to be labeled as “beef,” which is widely understood by consumers to be the flesh of a bovine animal, such as cattle, harvested for use as food, or

as “meat,” which is understood to be derived from animal tissue or flesh for use as food. *See Collective Exhibit 1* (definitions of “beef,” “meat,” and related terms).

Indeed, to eliminate the likelihood of confusion and to better inform consumers, USCA contends that labels indicating that a product is “beef” should be limited to product from cattle that have been born, raised, and harvested in the traditional manner. Similarly, products that are labeled as “meat” should be limited to those that are derived from the tissue or flesh of an animal harvested in the traditional manner. As such, USCA requests that FSIS exclude man-made or artificially manufactured products that are not derived from animals born, raised, and harvested in the traditional manner from the definition of both beef and meat. This includes synthetic products from plant, insects, and other non-animal components, as well as any product grown in labs from animal cells.

Pursuant to the statutory and regulatory procedures for filing a petitions with the FSIS, the required information and supporting documentation are provided herein and below. *See* 5 U.S.C. § 553(e); *see also* 7 C.F.R. § 1.28; 9 C.F.R. § 392 & §§ 392.3-392.4.

I. STATEMENT OF THE ACTION REQUESTED

USCA requests that FSIS limit the definition of beef to product from cattle born, raised, and harvested in the traditional manner. Specifically, FSIS should require that any product labeled as “beef” come from cattle that have been born, raised, and harvested in the traditional manner, rather than coming from alternative sources such as a synthetic product from plant, insects, or other non-animal components and any product grown in labs from animal cells.

USCA further requests that the broader definition of “meat” also be limited to the tissue or flesh of animals that have been harvested in the traditional manner. This would similarly prohibit product from alternative sources such as a synthetic product from plant, insects, or other non-animal components and any product grown in labs from animal cells from being labeled as “meat.”

The requested definition of “beef” and “meat” should be applicable to all products that use or might use the designation “beef” (or “meat” when marketed as a beef product) regardless of the country of origin. In other words, the definitions should not be limited to just U.S. product.

The above definitions should be added to the FSIS’ Food Standards and Labeling Policy Book. The Policy Book, which may be updated to reflect current policy developments, is “intended to be guidance to help manufacturers and prepare product labels that are truthful and not misleading.” *See* “Food Standards and Labeling Policy Book,” U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program and Employee Development (Aug. 2005) (“FSIS Policy Book”) at Preface, excerpts included in **Exhibit 2** attached hereto.

II. STATEMENT OF INTEREST

USCA is a national organization committed to presenting an effective voice for the U.S. cattle industry and promoting ranching in the United States. USCA is committed to promoting the interests of cattlemen in the United States on issues including the creation and maintenance of the Country of Origin Labeling program, the implementation of a national system of animal disease traceability, and ongoing work to address necessary reforms within the mandatory Beef Checkoff program. USCA is a non-profit corporation registered in Montana with members in twenty-seven states nationwide.

USCA's members include, among others, cow-calf operators, backgrounders, and independent feedlots. Cow-calf operators are ranchers and farmers who have herds of mother cows and who handle calves from birth to the weaning stage, typically five to ten months. Backgrounders, also known as stocker/yearling operators, are ranchers and farmers who handle cattle after the cow-calf stage up to the point of having cattle ready for final finishing at a feedlot, typically until twelve to twenty months of age. Feedlots finish cattle in terms of weight gain for the final three to five months and hold cattle until purchase by slaughterers. Some ranchers are involved in more than one stage (*e.g.*, may raise a calf from birth to fully finished and ready to go to the packing plant). In a born/raised/slaughtered information system, USCA members are involved in the born and/or raised phases.

USCA is concerned with the recent introduction and development of alternative products that are being marketed or may be marketed as though they are "beef". Synthetic products, comprised of plants, insects and other components *not* from animals, are already being sold in restaurants and retail markets as a form of "beef" or meat product. Additional products, most notably products grown in laboratories from animal cells, are under development. Though initial costs for these products were exorbitantly high, costs are rapidly decreasing and lab produced "beef" products are expected to be commercially sold by 2020.

Consistent with USCA's long standing position, USCA maintains that the FSIS should define "beef" (and "meat" when marketed as a beef product) as product from cattle born, raised, and harvested in the traditional manner to exclude any and all alternative products from using the term when not so derived.

III. STATEMENT OF THE GROUNDS FOR GRANTING THE PETITION

A. Legal Basis for Requested Actions

U.S. citizens have the right to petition the government to add, amend, or repeal rules under the Administrative Procedure Act (5 U.S.C. § 553(e)). Citizens may petition to amend U.S. Department of Agriculture (USDA) rules specifically under 7 C.F.R. § 1.28 and 9 C.F.R. § 392.

FSIS has primary responsibility for the regulation of food labeling for meat producers under the Federal Meat Inspection Act (FMIA). The FMIA states that meat or meat food

products shall be “misbranded” if its “labeling is false or misleading in any particular.” *See* 21 U.S.C. § 601(n)(1).

Products are considered to be mislabeled where, amongst other things, they are “offered for sale under the name of another food,” are “an imitation of another food, unless {the} label bears, in type of uniform size and prominence, the word ‘imitation’ and immediately thereafter, the name of the food imitated,” or “purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations” without conforming to the applicable definition and standard. *Id.* at § 601(n)(2)-(3), (7).

FSIS regulations for the “labeling and preparation of standardized products” further provide that “{a}ny product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products{.}” *See* 9 C.F.R. § 319.1.

Currently, FSIS regulations at 9 C.F.R. §§ 412.1 – 412.2 require that modifications to the labeling requirements be submitted to the FSIS for approval. The FSIS considers labeling claims for meat on a case-by-case basis.

Pursuant to this legal authority, USCA requests that the Secretary of Agriculture make the aforementioned changes to the Food Standards and Labeling Policy Book outlined in the Statement of Action Requested. *See* Section I, *supra*.

B. Consumer Perceptions With Respect to Alternative Products Labeled as “Beef” or “Meat”

Current labeling practices may cause consumer confusion in the market place. To demonstrate consumer perceptions with respect to “beef” and “meat,” we first explain the definition of the terms as proffered by a variety of sources including common dictionary definitions and the U.S. Department of Agriculture (USDA), which are widely understood by consumers. We next present the Federal Trade Commission’s “Truth in Advertising” standard, which requires that advertisements be truthful, not misleading, and, where possible, backed by scientific evidence. Finally, we show the facial confusion caused by current labeling practices based on recent articles, advertisements, and menus, as well as U.S. Food and Drug Administration (FDA) precedent.

i. The Definitions of “Beef” and “Meat”

Beef, meat, and related products have been defined by a variety of sources, including dictionaries, U.S. statute, and the USDA’s Agriculture and Marketing Service (AMS) and FSIS regulations. *See* **Collective Exhibit 1** (definitions of “beef,” “meat,” and related terms). These definitions are not applicable to alternative products, which, as discussed in more detail below, are not derived from animals harvested in the traditional manner.

1. Common dictionary definitions

Common dictionary definitions of the term “beef” indicate that the term refers to the meat of a slaughtered bovine animal. Specifically, the Merriam-Webster Dictionary defines beef as “the flesh of an adult domestic bovine (such as a steer or cow) used as food,” or alternatively as “a steer or cow fattened.” *See Beef Definition*, Merriam-Webster.com (last visited Jan. 29, 2018), part of **Collective Exhibit 1**. Oxford Dictionary similarly defines beef as “flesh of a cow, bull, or ox, used as food” or “{a} cow, bull, or ox fattened for its meat.” *See Beef Definition*, OxfordDictionaries.com (last visited Jan. 29, 2018), part of **Collective Exhibit 1**. *Accord Beef Definition*, dictionary.cambridge.org (last visited Jan. 29, 2018) (defining “beef” as “the flesh of cattle eaten as meat”), part of **Collective Exhibit 1**.

Significantly, other dictionaries clarify that beef is derived from bovine animals that have been “killed” or “slaughtered” for their meat. *See, e.g., Beef Definition*, Dictionary.com (last visited Jan. 29, 2018) (defining beef as “the flesh of a cow, steer, or bull raised and *killed* for its meat”); *Beef Definition*, TheFreeDictionary.com (last visited Jan. 29, 2018) (defining beef as the “flesh of a *slaughtered* full-grown steer, bull, ox, or cow”) (emphasis added), part of **Collective Exhibit 1**.

The aforementioned sources generally define “meat” as animal tissue or flesh used as food. *See, e.g., Meat Definition*, Merriam-Webster.com (last visited Jan. 30, 2018) (“animal tissue considered especially as food”); *Meat Definition*, OxfordDictionaries.com (last visited Jan. 30, 2018) (“flesh of an animal, typically a mammal or bird, as food”), part of **Collective Exhibit 1**.

The two alternative products highlighted above, *i.e.*, a synthetic product from plant and/or insects and a lab grown product from an animal cell, do not constitute “beef” or “meat” pursuant to these standard dictionary definitions. Indeed, in each definition discussed above, beef is defined as the derivative of a bovine animal, while meat is described as animal tissue or flesh. The synthetic product, however, is derived from plants, insects and other non-animal components. In addition, the definitions emphasize that beef is from fattened cattle that have been killed or slaughtered. Lab grown product, however, is artificially grown in a petri dish from animal cells. As such, these alternative products do not meet the traditional definition of “beef” or “meat” and are in fact marketed as vegan.

As previously noted, pursuant to FSIS regulations, “{a}ny product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products{.}” *See* 9 C.F.R. § 319.1. The common names of “beef” and “meat” are widely understood by consumers to be the tissue or flesh of animals that have been slaughtered for food. As such, any products that are labeled as “beef” or “meat” that are neither derived from animals, nor slaughtered in the traditional manner are misbranded. If synthetic or lab grown “beef” is intended to be an imitation of traditional beef, it must be labeled as such. 21 U.S.C. § 601(n)(3).

2. Federal statutory and regulatory definitions

The definitions of “beef,” “meat,” and other related products, as set forth in federal statutes and regulations, are generally consistent with the standard dictionary definitions and supports USCA’s position with respect to alternative products.

The term “meat food product” is defined in the Federal Meat Inspection Act (FMIA) as “any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats.” *See* 21 U.S.C. § 601(j). “Prepared” meat refers to meat that has been “slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.” *Id.* at § 601(l).

USDA AMS regulations specifically define “beef” as the “flesh of cattle,” which is in turn defined as “live domesticated bovine animals regardless of age.” 7 C.F.R. § 1260.118-119. Beef products are defined in the AMS regulations as “edible products produced in whole or in part from beef{.}” 7 C.F.R. § 1260.120. Meat is more broadly defined by the AMS regulations as “the edible part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, and which is intended for human food{.}” 7 C.F.R. § 98.2.

The USDA FSIS regulations further define specific beef products, including ground beef, hamburger, and beef patties. *See* 9 C.F.R. § 319.15. Specifically, ground beef is defined as “chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat{,}” while hamburger and beef patties are defined as “chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings.” *See id.* at 9 C.F.R. § 319.15(a)-(c).

Though the general term “beef” is not defined in the FSIS Policy Book, specific beef products, such as “beef a la mode,” “beef and gravy,” “beef burgundy or bourguignonne,” “beef marsala,” “beef roulade,” and “beef slices a-la-pizzaiola,” are included. *See* FSIS Policy Book at 9, 16, and 21, excerpts included in **Exhibit 2** attached hereto. The definitions of these and other beef products included in the Policy Book indicate a minimum percentage of beef content; for example, each of the aforementioned products must contain at least 50 percent beef. *Id.* Certain beef products defined by the Policy Book further contemplate that the bovine animal will be slaughtered. The term “aged beef,” for example, is defined in part as beef “maintained in a fresh unfrozen state for a minimum of 14 days from the day of slaughter.” *Id.* at 9.

The FSIS Policy Book likewise contains definitions of various meat products, such as “meat casseroles,” “meat curry,” “meat pies,” “meat spreads,” and “meatballs.” *See* FSIS Policy Book at 106, and 108-10, excerpts included in **Exhibit 2** attached hereto. As with the various beef products outlined above, there are similar minimum meat percentage requirements for these meat products. *See id.*

As previously noted, a product is misbranded where it fails to conform to a definition or standard prescribed by regulation. *See* 21 U.S.C. § 601(n)(7). In this case, the

alternative products meet neither the statutory definition of “meat food product,” nor the USDA regulatory definitions of beef, beef products, and meat. The synthetic product is comprised of plants, insects and other non-animal components and, as such, does not contain meat from the flesh of cattle or any other animal pursuant to the requirements in the definitions above. In addition, the lab grown product is not derived from cattle that have been slaughtered in the traditional manner, as contemplated by the definitions of beef products outlined in the FSIS Policy Book.

By way of analogy, the FDA has found similar vegan imitations of products to be misbranded when they purport to be the standardized food item as defined by the regulations. *See Collective Exhibit 3* attached hereto (FDA case precedent on vegan alternatives to standardized food items). Most notably, in 2015, the FDA issued a warning to Hampton Creek Foods for its use of a misleading name and imagery of a cracked egg on the labels of its vegan “Just Mayo” and “Just Mayo Sriracha” products. *See “Hampton Creek Foods Warning Letter,”* FDA Department of Health and Human Services (Aug. 12, 2015), included in *Collective Exhibit 3* attached hereto. Specifically, the FDA found the company’s use of the term “mayo” to be impermissible because the product did not contain eggs as required by the regulatory definition of “mayonnaise.” *Id.* at ¶ 3. The FDA determined that the “{t}he use of the term ‘mayo’ in the product names and the image of an egg may be misleading to consumers because it may lead them to believe that the products are the standardized food, mayonnaise, which must contain eggs as described under {the regulations}.” *Id.*

Though the company was ultimately allowed to continue using the trade name “Just Mayo,” the FDA required it to “use bigger type on the front of the label for the list of product attributes like ‘egg-free.’” *See* Stephanie Strom, “F.D.A. Allows Maker of Just Mayo to Keep Product’s Name,” *NY Times* (Dec. 17, 2015), included in *Collective Exhibit 3* attached hereto.

ii. Applicability of the FTC’s “Truth in Advertising” Standard

The Federal Trade Commission (FTC) regulates unfair or deceptive acts, including false and misleading advertising of foods, drugs, devices, and cosmetics. *See* 15 U.S.C. § 52; *see also Collective Exhibit 4* attached hereto (explanation of the FTC’s “Truth in Advertising” standard).

The FTC regulations prohibit advertisements for food products that are “misleading in a material respect.” *See id.* at § 55(a)(1). As such, the FTC applies a “truth in advertising” standard, *i.e.*, ads must be “truthful, not misleading, and, when appropriate, backed by scientific evidence.” *See* “Truth in Advertising,” *FTC.gov* (last visited Jan. 29, 2018), part of *Collective Exhibit 4*. This standard is applicable to all advertisements, including ads that appear in newspapers and magazines, online, or on billboards. *Id.*

In determining whether an advertisement is misleading, the FTC will consider both “representations made or suggested by statement, word, design, device, sound, or any combination thereof,” as well as “the extent to which the advertisement fails to reveal facts material in the light of such representations{.}” *See* 15 U.S.C. § 55(a)(1). The

FTC's "Policy Statement on Deception" further notes that an ad is deceptive if it is "likely to mislead consumers acting reasonably under the circumstances" and is "important to a consumer's decision to buy or use the product." *See* FTC Policy Statement on Deception (Oct. 14, 1983), part of **Collective Exhibit 4**.

The FTC has rigorously enforced its "truth in advertising" standard in context of food products, such as nutritional and dietary supplements and pet food. *See, e.g.*, Press Release, "Mars Petcare Settles False Advertising Charges Related to Its Eukanuba Dog Food," FTC.gov (Aug. 4, 2016); Press Release, "FTC Approves Final Consent Orders Settling Charges that Companies Deceptively Claimed Their Genetically Modified Nutritional Supplements Could Treat Diseases," FTC.gov (May 12, 2014), part of **Collective Exhibit 4**.

The FTC "truth in advertising" standard further supports USCA's position with respect to the alternative products reviewed. Specifically, the marketing of a plant-based burger as "beef" or "meat" is potentially deceptive because consumers would reasonably expect products labeled as such to be derived from animals slaughtered in the traditional manner. However, none of the alternative products derived from plants, insects or other non-animal sources and currently being sold in restaurants or grocery stores as a form of "burger" actually contain beef or any other meat, as it is defined by standard dictionaries, U.S. statutes, and USDA regulations. As demonstrated below, moreover, some of these synthetic products are being sold along-side traditional beef products in the market place, increasing the likelihood of consumer confusion.

iii. Labeling of Alternative Products as "Beef" and "Meat" in the Market Place

The absence of a definition of "beef" or "meat" and specific rules and parameters as to what constitutes them is resulting in mislabeling and may lead to consumer confusion. Without more stringent guidance as to what constitutes beef, such mislabeling will continue in the market place.

As previously noted, USCA is concerned with two categories of alternative products under development or currently being sold in the United States: (1) synthetic products made from alternative proteins, and (2) "lab grown beef" from animal cells, also known as "*in vitro*," "bio meat," "clean meat," or "cultured meat." Both categories of alternative products should not be permitted to use the "beef" label. These alternative products are *not* from an animal, born, raised and harvested in the traditional manner and, as such, do not meet the standard, statutory, and regulatory definitions of beef and beef products.

As discussed below, both the synthetic product and the lab grown product from animal cells directly compete, or will soon directly compete, against actual beef products that are born, raised and harvested in the traditional manner. *See* **Collective Exhibit 5** attached hereto (the development and labeling of the alternative products in the market place). Thus, in USCA's view both categories should be excluded from the definition of "beef."

Currently, there is no definition of what constitutes a “beef” or “meat” product. In light of the new market for synthetic products, new regulations should be adopted limiting the “beef” and “meat” labels to animals born raised, harvested, and processed in the traditional way.

1. Synthetic beef products

Synthetic products, which are derived from plants, insects and other non-animal components, are currently being sold in retail stores, specialty restaurants, and national chain restaurants.

One example of a synthetic product is one produced by Impossible Foods, which promotes “a plant-based burger that smells, tastes, looks and even feels like ground beef.” See Matt Simon, “The Impossible Burger: Inside the Strange Science of the Fake Meat that ‘Bleeds,’” *Wired.com* (Sept. 20, 2017), part of **Collective Exhibit 5**. On its website, Impossible Burger labels a photo of its meatless product, which is identical to raw ground beef in appearance, as “For the Love of Meat.” See Impossible Burger, *ImpossibleFoods.com* (last visited Jan. 29, 2018), part of **Collective Exhibit 5**. As previously discussed, “meat food product{s}” are defined by statute as products “made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats.” See Section B.i.2., *supra*; see also 21 U.S.C. § 601(j). USDA regulations also define meat as “the edible part of the muscle of any cattle, sheep, swine, or goats, . . . which is intended for human food{.}” See Section B.i.2., *supra*; see also 7 C.F.R. § 98.2. Despite being labeled as such, the Impossible Burger does not contain meat as define by statute and USDA regulations.

Similarly, Southern California’s Beyond Meat sells a “plant-based burger that looks, cooks, and tastes like a traditional burger” in retail stores and restaurant chains. See Jill Ettinger, “TGI Fridays to Run Meatless Monday Campaign After Vegan Burger Launch,” *Organicauthority.com* (Jan. 9, 2018), part of **Collective Exhibit 5**. To directly compete with traditional beef products, Beyond Meat strategically merchandises its products adjacent to traditional meat in grocery stores. *Id.* Indeed, Beyond Meat’s website shows that its burger patties are virtually indistinguishable when sold next to traditional ground beef. See “The Beyond Burger,” *BeyondMeat.com* (last visited Jan. 29, 2018), part of **Collective Exhibit 5**. Like the Impossible Burger, Beyond Meat patties are labeled as “meat” even though they do not meet the statutory definition of a “meat food product,” the regulatory definition of “meat,” nor contain any meat as so defined. See Section B.i.2. *supra*; see also 21 U.S.C. § 601(j).

In addition, Beyond Meat sells “Beefy,” “Beyond Beef Crumbles,” which are advertised as a “beefy kick for any ground beef recipe.” See “Products: Beyond Beef Crumble,” *BeyondMeat.com* (last visited Jan. 29, 2018), part of **Collective Exhibit 5**. These products do not contain beef, but rather non-meat ingredients such as “Pea Protein Isolate,” “Rice Flour,” and “Yeast Extract.” *Id.* As discussed above, USDA regulations define beef as the “flesh of cattle” and ground beef as “chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat{.}” See Section B.i.2. *supra*; see also 7 C.F.R. § 1260.119; 9 C.F.R. § 319.15(a). Beyond Beef

Crumbles do not comport with these regulatory definitions despite being labeled as “beef” and as a substitute for “ground beef.” *Id.*

In addition, as with the FDA case involving Just Mayo and Just Mayo Sriracha products, where the labeling of eggless, vegan mayonnaise with imagery of a cracked egg was found to be misleading, Section B.i.2 *supra*, Beyond Beef labels its “Beyond Beef Crumble” with the image of a cow. *See* “Products: Beyond Beef Crumble,” BeyondMeat.com (last visited Jan. 29, 2018), part of **Collective Exhibit 5**. For the same reasons and concerns articulated in the FDA mayo case, this label should not be permitted since it is misleading to consumers.

Fueled by investments from philanthropists like Bill Gates and traditional meat companies like Tyson Foods Inc., both Impossible Burger and Beyond Meat have rapidly expanded and are becoming more prevalent in the market place. *See* Shruti Singh, “Bill Gates and Richard Branson Back Startup That Grows ‘Clean Meat,’” Bloomberg.com (Aug. 23, 2017), part of **Collective Exhibit 5**. For example, Impossible Burger is dramatically increasing its production capacity with a new factory that will have the capacity to produce 12 million pounds of burgers per year. *See* Adele Peters, “In Its New Factory, Impossible Foods Will Make 12 Million Pounds Of Plant-Based Burgers A Year,” FastCompany.com (Mar. 29, 2017), part of **Collective Exhibit 5**. Likewise, Beyond Beef was recently added to the menu at more than 500 TGI Fridays chains nation-wide. *See* Jill Ettinger, “TGI Fridays to Run Meatless Monday Campaign After Vegan Burger Launch,” Organicauthority.com (Jan. 9, 2018), part of **Collective Exhibit 5**. Notably, the TGI Fridays’ menu simply lists “The Beyond Meat Cheeseburger” alongside traditional burgers with a picture that is indistinguishable from the other, traditional beef burgers on the menu. *See* TGI Fridays Menu, tgifridays.com (last visited Jan. 30, 2018), part of **Collective Exhibit 5**.

The proliferation of synthetic products is expected to continue, with an increasing number of synthetic products entering the market and displacing the market share of traditional beef products. Indeed, as noted in one article, “alternative proteins, such as insects ... are on the verge of becoming mainstream and ‘stealing’ growth from traditional meat products.” Rebecca Howard, “Beef + Lamb explores ‘alternative protein’ options,” nzherald.co.nz (Nov. 27, 2017), part of **Collective Exhibit 5**.

2. Lab grown product

Lab grown product from animal cells, also known as “*in vitro*,” “bio meat,” “clean meat,” or “cultured meat,” is a second category of non-beef product that is in development. *See, e.g.*, Rachel Roberts, “China signs \$300m deal to buy lab-grown meat from Israel in move welcomed by vegans,” Independent.co.uk (Sept. 2017), part of **Collective Exhibit 5**. Though lab grown product currently relies on animal cells, a totally synthetic substitute is being developed, which will cater to vegans. *Id.* In USCA’s view, such artificially created products, regardless of whether derived from animal cells, should not be permissibly labeled as “beef,” which is widely understood to be a derivative of cattle harvested in the traditional manner. *See* Section B.i.1., *supra*.

Though lab grown product is not yet available in restaurants or at the retail level, its development has been backed by prominent investors like Bill Gates and Cargill Inc. and, consequently, the cost of the lab grown product is becoming more commercially feasible. *See* Ido Efrati, “Israeli Institutions Working to Bring Cultured Meat From Lab to Plate,” Haaretz.com (Apr. 30, 2017); Shruti Singh, “Bill Gates and Richard Branson Back Startup That Grows ‘Clean Meat,’” Bloomberg.com (Aug. 23, 2017), part of **Collective Exhibit 5**.

Prominent producers of lab grown product include Memphis Meats and Mosa Meats, which seeks to create an \$11 lab burger for commercial sale by 2020. *Id.*; *see also* “Where’s the beef?: The market for alternative-protein products,” Economist.com (Feb. 2, 2017), part of **Collective Exhibit 5**. Lab grown products are likely to become more prevalent in the market place and thus take market share from natural meat products harvested in the traditional manner.

USCA requests that any lab grown product (whether from an animal cell or from other sources) be excluded from the definition of “beef” and “meat.”

IV. CONCLUSION

USCA has long advocated for additional beef labeling requirements to better inform consumers that beef is of U.S. origin. A closely related concern is what constitutes “beef” and “meat” more generally.

In recent years, there have been major investments in synthetic product and in products grown in laboratories using animal cells. Such products should *not* be permitted to be marketed as beef or as meat. This distinction should not be limited to just U.S. beef and meat, but rather applicable to all product regardless of the country of origin.

The “beef” and “meat” labels should inform consumers that the products are from animals harvested in the traditional manner, as opposed to derived from alternative proteins or artificially grown in laboratories. As such, the definitions of “beef” and “meat” should be limited to animals born, raised, and processed in the traditional manner, regardless of the country of origin. Synthetic products and products grown in labs from animal cells should thus not qualify to be labeled as “beef” or as “meat.”

USCA requests that the Secretary of Agriculture make the aforementioned changes to the Food Standards and Labeling Policy Book.

Respectfully submitted,



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Dated: February 9, 2018

LIST OF EXHIBITS

1. Definitions of “beef,” “meat,” and related terms

- *Beef Definition*, Merriam-Webster.com (last visited Jan. 29, 2018)
- *Beef Definition*, OxfordDictionaries.com (last visited Jan. 29, 2018)
- *Beef Definition*, dictionary.cambridge.org (last visited Jan. 29, 2018)
- *Beef Definition*, Dictionary.com (last visited Jan. 29, 2018)
- *Beef Definition*, TheFreeDictionary.com (last visited Jan. 29, 2018)
- *Meat Definition*, Merriam-Webster.com (last visited Jan. 30, 2018)
- *Meat Definition*, OxfordDictionaries.com (last visited Jan. 30, 2018)

2. “Food Standards and Labeling Policy Book,” U.S. Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program and Employee Development (Aug. 2005) (excerpts)

3. FDA Case Precedent on Vegan Alternatives

- “Hampton Creek Foods Warning Letter,” FDA Department of Health and Human Services (Aug. 12, 2015)
- Stephanie Strom, “F.D.A. Allows Maker of Just Mayo to Keep Product’s Name,” NY Times (Dec. 17, 2015)

4. Explanation of the FTC’s “Truth in Advertising” standard

- “Truth in Advertising,” FTC.gov (last visited Jan. 29, 2018)
- FTC Policy Statement on Deception (Oct. 14, 1983)
- Press Release, “Mars Petcare Settles False Advertising Charges Related to Its Eukanuba Dog Food,” FTC.gov (Aug. 4, 2016)
- Press Release, “FTC Approves Final Consent Orders Settling Charges that Companies Deceptively Claimed Their Genetically Modified Nutritional Supplements Could Treat Diseases,” FTC.gov (May 12, 2014)

5. The development and labeling of “fake meat” in the market place

- Matt Simon, “The Impossible Burger: Inside the Strange Science of the Fake Meat that ‘Bleeds,’” Wired.com (Sept. 20, 2017)
- Jill Ettinger, “TGI Fridays to Run Meatless Monday Campaign After Vegan Burger Launch,” Organicauthority.com (Jan. 9, 2018)
- “The Beyond Burger,” BeyondMeat.com (last visited Jan. 29, 2018)
- “Products: Beyond Beef Crumble,” BeyondMeat.com (last visited Jan. 29, 2018)
- Shruti Singh, “Bill Gates and Richard Branson Back Startup That Grows ‘Clean Meat,’” Bloomberg.com (Aug. 23, 2017)

- Adele Peters, “In Its New Factory, Impossible Foods Will Make 12 Million Pounds Of Plant-Based Burgers A Year,” [FastCompany.com](#) (Mar. 29, 2017)
- TGI Fridays Menu, [tgifridays.com](#) (last visited Jan. 30, 2018)
- Rebecca Howard, “Beef + Lamb explores ‘alternative protein’ options,” [nzherald.co.nz](#) (Nov. 27, 2017)
- “China signs \$300m deal to buy lab-grown meat from Israel in move welcomed by vegans,” [Independent.co.uk](#) (Sept. 2017)
- Ido Efrati, “Israeli Institutions Working to Bring Cultured Meat From Lab to Plate,” [Haaretz.com](#) (Apr. 30, 2017)
- “Where’s the beef?: The market for alternative-protein products,” [Economist.com](#) (Feb. 2, 2017)

Exhibit 1



¹beef

noun \ 'bēf \

Popularity: Bottom 50% of words | Updated on: 23 Jan 2018

☒ TELL US ABOUT YOURSELF

Examples: BEEF in a Sentence



Definition of BEEF

plural **beefs** \ 'bēfs \ or **beeves** \ 'bēvz \

1 : the flesh of an adult domestic bovine (such as a steer or cow) used as food

2 **a** : an ox, cow, or bull in a full-grown or nearly full-grown state; *especially* : a steer or cow fattened for food quality
Texas *beeves* a herd of good *beef*
b : a dressed carcass of a beef animal

3 : muscular flesh : **BRAWN**

4 *plural* **beefs** : **COMPLAINT**

Definition of *beef* in English:

beef

NOUN

- 1 *mass noun* The flesh of a cow, bull, or ox, used as food.

'there was the smell of roast beef'

as modifier 'beef cattle'

[More example sentences](#)

- 1.1 *Farming count noun* A cow, bull, or ox fattened for its meat.

'a beef sent to the abattoir'

[More example sentences](#)

[Synonyms](#)

- 2 *informal mass noun* Flesh with well-developed muscle.

'he needs a little more beef on his bones'

[More example sentences](#)

[Synonyms](#)

- 2.1 Strength or power.

'he was brought in to give the team more beef'

[More example sentences](#)

[Synonyms](#)

- 2.2 The substance of a matter.

'it's more a sketch than a policy—where's the beef?'

[More example sentences](#)

- 3 *informal* A complaint or grievance.

'he has a beef with education: it doesn't teach the basics of investing'

[More example sentences](#)

[Synonyms](#)

- 4 *US informal* A criminal charge.

'getting caught with pot in the sixties was a narco beef'

[More example sentences](#)

[Synonyms](#)

VERB

informal

no object **Complain.**

'he was beefing about how the recession was killing the business'

[More example sentences](#)

[Synonyms](#)

Phrasal Verbs

beef something up

Give more substance or strength to something.

'cost-cutting measures are planned to beef up performance'

[More example sentences](#)

[Synonyms](#)

Origin

Middle English: from Old French boef, from Latin bos, bov- 'ox'.

Pronunciation

beef /bi:f/

Definition of “beef” - English Dictionary

American

Contents

“beef” in American English

See all translations

beef

noun US /bif/

beef *noun* (MEAT)

[U] **the flesh of cattle eaten as meat:**

a roast beef sandwich

beef *noun* (COMPLAINT)

[C] SLANG **a complaint:**

My beef is, how come I'm not making as much as you?

beef

verb [I] US /bif/ SLANG

beef *verb* [I] (COMPLAIN)

to complain:

Stop beefing about having to work late – you're not the only one.

Phrasal verb(s)

(Definition of
"beef" from

beef up something

the **Cambridge Academic Content Dictionary** © Cambridge University Press)

definitions beef

beef

[beef]

Examples

Word Origin

See more synonyms on Thesaurus.com

noun, plural **beeves** [beevz] (Show IPA), for 2; **beefs** for 4.

1. the flesh of a cow, steer, or bull raised and killed for its meat.
2. an adult cow, steer, or bull raised for its meat.
3. *Informal.*
 - a. brawn; muscular strength.
 - b. strength; power.
 - c. weight, as of a person.
 - d. human flesh.

beef

Also found in: [Thesaurus](#), [Medical](#), [Acronyms](#), [Idioms](#), [Encyclopedia](#), [Wikipedia](#).

Related to beef: [beef stew](#), [beef Stroganoff](#)

beef (bēf)

n. pl. **beeves** (bēvz) or **beef**

1.

a. A full-grown steer, bull, ox, or cow, especially one intended for use as meat.

b. The flesh of a slaughtered full-grown steer, bull, ox, or cow.

2. *Informal* Human muscle; brawn.

3. *pl. beefs Slang* A complaint.

intr.v. **beefed**, **beef·ing**, **beefs Slang**

To complain.

Phrasal Verb:

beef up *Informal*

To make or become greater or stronger: *beef up the defense budget.*

[Middle English, from Old French *buef*, from Latin *bōs*, *bov-*; see [g^wou-](#) in [Indo-European roots](#).]

Word History: As has often been remarked, the great social disparities of medieval European society are revealed by—most of whom could speak French or at least admired French culture—and the Modern English terms for these meats are uniformly of French origin. (The French sources of the English words speaking peasants who actually raised the animals—and who presumably subsisted on mostly vegetarian fare—continued to use the original Germanic words *ox*, *swine*, *calf*, and *sheep* when talking in the barnyard, and so the animal's European root **g^wou-*, "cow." This root has descendants in most of the branches of the Indo-European language family. Among those descendants is the Latin word *bōs*, "cow," whose stem form, *bov-*, eventually

American Heritage® Dictionary of the English Language, Fifth Edition. Copyright © 2016 by Houghton Mifflin Harcourt Publishing Company. Published by Houghton Mifflin Harcourt Publishing Company. All rights reserved.

beef (bi:f)

npl **beeves** (bi:vz) *pl* **beefs**

1. (Cookery) the flesh of various bovine animals, esp the cow, when killed for eating

2. (Breeds) an adult ox, bull, cow, etc, reared for its meat

3. *informal* human flesh, esp when muscular

4. a complaint

vb

5. (*intr*) *slang* to complain, esp repeatedly: *he was beefing about his tax.*

6. *informal* (often foll by: *up*) to strengthen; reinforce

[C13: from Old French *boef*, from Latin *bōs* ox; see *cow*¹]

Collins English Dictionary – Complete and Unabridged, 12th Edition 2014 © HarperCollins Publishers 1991, 1994, 1998, 2000, 2003, 2006, 2007, 2009, 2011, 2014

beef (bif)

n., pl. **beeves** (bēvz) for 2; **beefs** for 4, *n.*

1. the flesh of a cow, steer, or bull raised and killed for its meat.

2. an adult cow, steer, or bull raised for its meat.

3. *Informal.*

a. brawn; muscular strength.

b. human flesh.

4. *Slang.* a complaint.

v.i.

5. *Slang.* to complain; grumble.

6. **beef up**, to add strength, numbers, force, etc., to.

[1250–1300; Middle English < Anglo-French *beof*, Old French *boef* < Latin *bovem*, acc. of *bōs* ox, cow; akin to **cow** ¹]

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beef

Past participle: beefed

Gerund: beefing

Imperative ▼

Imperative
beef
beef

Collins English Verb Tables © HarperCollins Publishers 2011



meat

noun \ 'mēt \

Popularity: Top 30% of words | Updated on: 23 Jan 2018

☒ TELL US ABOUT YOURSELF

Examples: MEAT in a Sentence



Definition of MEAT

- 1 **a** : **FOOD**; *especially* : solid food as distinguished from drink
b : the edible part of something as distinguished from its covering (such as a husk or shell)
- 2 : animal tissue considered especially as food:
a : **FLESH** 2b; *also* : flesh of a mammal as opposed to fowl or fish
b : **FLESH** 1a; *specifically* : flesh of domesticated animals
- 3 *archaic* : ¹**MEAL** 1; *especially* : **DINNER**
- 4 **a** : the core of something : **HEART**
b : **PITH** 2b a novel with *meat*
- 5 : favorite pursuit or interest

—**meated** \ 'mē-təd \ *adjective*

—**meatless** *adjective*

SEE WORDS FROM THE SAME YEAR

See *meat* defined for English-language learners

See *meat* defined for kids

Explore M-W



alt-59c94ad823f29

'Meat Sweats': The
Cookout's Worst
Nightmare



meatspace

What Is 'Meatspace'?

Examples of MEAT in a Sentence

The restaurant serves a variety of *meats*.

The real *meat* of the book is found in its discussion of his economic plan.

Recent Examples of MEAT from the Web

The Suburban House restaurant — a Kosher-style Pikesville landmark known for its matzo ball soup, smoked

- Colin Campbell, *baltimoresun.com*, "Suburban House in Pikesville permanently closed, owner says," 27 Dec. 2017

The menu offers traditional items but also *meat* and seafood specials and frequently new side dishes.

- Joanne Kempinger Demski, *Milwaukee Journal Sentinel*, "Sandra's on the Park Sliced Brussels Sprouts: You Asked for It," 26 Dec. 2017

Add bread crumb mixture to *meat* and stir until just combined.

- Darlene Zimmerman, *Detroit Free Press*, "Chicken cocktail meatballs get a spicy kick from enchilada sauce," 23 Dec. 2017

These example sentences are selected automatically from various online news sources to reflect current usage of the word 'meat.' Views expressed in the examples do not represent the opinion of Merriam-Webster or its editors. [Send us feedback](#).

Origin and Etymology of MEAT

Middle English *mete* "food, meal," going back to Old English, going back to Germanic **mati-* (whence Old Saxon *meti*, *mat* "food," Old High German *maz*, Old Norse *matr*,

MEAT Synonyms

Synonyms

flesh

Other Food Terms

Reuben, calamari, chuck, curry, edamame, foie gras, hummus, leaven, nonpareil, peel

Definition of *meat* in English:

meat

NOUN

mass noun

- 1 The flesh of an animal, typically a mammal or bird, as food (the flesh of domestic fowls is sometimes distinguished as poultry)

'pieces of meat'

'place meat and poultry in the refrigerator immediately'

as modifier 'meat pies'

count noun 'cold meats'

[More example sentences](#)

[Synonyms](#)

- 1.1 The flesh of a person's body.

'this'll put meat on your bones!'

[More example sentences](#)

[Synonyms](#)

- 1.2 *North American* The edible part of fruits, nuts, or eggs.

[Example sentences](#)

- 1.3 **the meat of** The chief part of something.

'he did the meat of the climb on the first day'

[More example sentences](#)

[Synonyms](#)

- 2 *archaic* Food of any kind.

[Synonyms](#)

- 2.1 A meal.

'we have talked at meat with this stranger'

[More example sentences](#)

Phrases

be meat and drink to

- 1 Be a source of great pleasure to.

'meat and drink to me, this life is!'

- 2 Be a customary matter for.

'the commercial market-research business that is meat and drink to most pollsters'

More example sentences

easy meat

informal A person who is easily overcome or outwitted.

'with no family money to protect him, he was easy meat'

More example sentences

Synonyms

meat and potatoes

Basic and essential aspects.

'the club's meat and potatoes remains blues performers'

More example sentences

meat and two veg

- 1 A dish consisting of meat served with two varieties of vegetable.

- 2 A man's genitals.

Example sentences

one man's meat is another man's poison

proverb Things liked or enjoyed by one person may be distasteful to another.

Example sentences

Origin

Old English mete 'food' or 'article of food' (as in sweetmeat), of Germanic origin.

Pronunciation

meat /mi:t/

Exhibit 2



Food Safety
And Inspection
Service

Office of Policy, Program and
Employee Development

August 2005

Food Standards and Labeling Policy Book

Revised for Web Publication August 2005

Replaces Publication Dated May 2003 and Removal of Publication Dated 1996

PREFACE

The Policy Book is intended to be guidance to help manufacturers and prepare product labels that are truthful and not misleading. Compliance with the requirements set forth in this publication does not, in itself, guarantee an authorization. On receipt of the label application, consideration will be given to suitability of ingredients statements, preparation, and packaging so as not to mislead the consumer. Adherence to the product and label requirements in this Policy Book does not necessarily guarantee against possible infringement of all related patents, trademarks or copyrights.

Changes in this publication are to add new entries, correct errors, condense material, and reformat the entries for ease in reading and use. There will be updates of the publication to conform to changes in meat and poultry inspection standards and to reflect any current policy developments.

Errors found in this issue should be reported through channels to your district office.

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INTRODUCTION

This Policy Book is assembled in dictionary form and may be used in conjunction with the Meat and Poultry Inspection Regulations and the Meat and Poultry Inspection Manual, Directives and Notices. It is a composite of policy and day-to-day labeling decision, many of which do not appear in the above publications. They are subject to change and therefore a periodic updating of this book will take place.

Note: Red Meat

Required percentages of meat required for red meat products are shown on the basis of *fresh uncooked weight* unless otherwise indicated. For purposes of this Policy Book, whenever the terms beef, pork, lamb, mutton, or veal are used they indicate the use of skeletal muscle tissue from the named species (9 CFR 301.2).

Note: Poultry

Required percentages for poultry products are based on a *cooked deboned* basis unless otherwise stated. When the standards indicate “poultry”, the skin and fat are not to exceed natural proportions per (9 CFR 381.117(d)).

Applications for label approval should be addressed as follows:

USDA, FSIS, OPPED
Labeling and Consumer Protection Staff (LCPS)
1400 Independence Avenue, SW
Room 614 – Annex Building
Washington, DC 20250-3700

Product samples (only when requested by LCPS) should be packed with sufficient refrigerant to last until received. Shipping should be coordinated with requestor to assure delivery before 4:00 p.m. Friday.

Labeling and Consumer Protection Staff
1400 Independence Avenue, SW
Room 614 – Annex Building
Washington, DC 20250-3700

UPDATED ENTRIES SINCE LAST PUBLICATION

Corrections:

Aged
Aged Beef
Artificially Colored Products
Bratwurst
Bratwurst, Cured
Buffalo Style
Cereal
Chili Sauce with Meat
Chorizo, Fresh
Egg Roll with Meat
Egg Roll with Poultry
Enzymes – Proteolytic
Fajitas
Giblets and/or Necks Sold with Carcasses
Kiska, Kisba, Kishka, or Stuffed Derma
Labeling of Boneless Beef, Ham or Poultry Products
Labeling of Modified Breakfast Sausage, Cooked Sausage, and Fermented Sausage Products
 Identified by a Nutrient Content Claim
Labeling of Modified Substitute Versions of Fresh (Species) Sausage, Hamburger or Ground
 Beef Products
Pasty (Cornish Style)
Pizza Burger
Pizza Sauce with Sausage
Pizza Topping Containing Sausage
Pizza Topping Mix
Poultry Meat, Raw
Protective Coverings (Meat)
Serving Suggestion, Serve as Suggested and Similar Phrases
Solutions in Red Meat Products
Textured Vegetable Protein (TVP) Products-Fresh Meat or Poultry Meat Ratios
Yeast

Deletions:

Methyl Cellulose
Pizza, Combination or Deluxe
Select or Higher

Revisions:

Amenability
Cheese
Cheese Products Containing Meat
Fresh, "Not Frozen" and Similar Terms When Labeling Meat and Poultry Products
Grade Marks
Halal and Zabiah Halal
Kosher
Natural Claims
Pizza
Pizza Chicago Style
Pizza Containing Cheese Substitutes
Potato Sausage, Swedish Style, or Potato Ring or Potato Pudding
Pressure Sensitive Stickers and Indelible Ink
Weisswurst

Definitions:

Corrections: Previous entries that were inadvertently removed from last publication have been added back in, or typographical errors which have been corrected, and/or regulatory cites corrected

Deletions: Entries which have been removed

Revisions: Previous entries which have been revised to reflect current agency policy

ABBREVIATIONS

AMS	Agriculture Marketing Service
BHA	Butylated Hydroxyanisole (anti-oxidant)
BHT	Butylated Hydroxytoluene (anti-oxidant)
CRDSM	Calcium Reduced Dry Skim Milk
FDA	Food and Drug Administration
FR	French
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
GRAS	Generally Recognized as Safe
HVP	Hydrolyzed Vegetable Protein
IMPS	Institutional Meat Purchase Specifications
IT	Italian
LCPS	Labeling and Consumer Protection Staff
MPR	Moisture Protein Ratio
MSG	Monosodium Glutamate
NAMP	National Association of Meat Purveyors
NFDM	Nonfat Dry Milk
NOP	National Organic Program
OPPED	Office of Policy Program and Employee Development
PDBFT	Partially Defatted Beef Fatty Tissue
PDCB	Partially Defatted Chopped Beef
PDCP	Partially Defatted Chopped Poultry
PDPFT	Partially Defatted Pork Fatty Tissue
PER	Protein Efficiency Ratio
PFF	Protein Fat Free
pH	Measure of Acidity
PPM	Parts Per Million
SP	Spanish
TVP	Textured Vegetable Protein
URMIS	Uniform Retail Meat Identity Standards
USA	United States of America
USDA	United States Department of Agriculture
VPP	Vegetable Protein Product

ADDED SOLUTIONS (WITH JUICES):

Products with added solutions that are cooked in an impervious bag and as a result of the cooking contain free flowing juices that are not drained, should be labeled to reflect the solution and the juices, e.g., (“Roast Beef Contains up to 12 percent solution with Juices”).

ADDED SOLUTIONS (POULTRY) (BONELESS):

Boneless poultry products containing solutions can be labeled similarly to the PFF language for cured pork products, that is “Cured Chicken and Water Product X percent of Weight is Added Ingredients.” The terms “with natural juices” or “water added” are not permitted since both terms do not adequately convey the amount of solution added to the poultry products. Additionally, the term “with natural juices” is misleading when a solution is introduced into poultry product by means of marinating, soaking, injecting, tumbling, etc.

AGED:

Aging is the process by which fresh beef (carcasses or cuts) are held in a controlled environment for a specified period of time of slaughter, to allow enzymatic activity to degrade complex proteins and promote the development of flavor and tenderness. The term “Aged” on a label must be qualified, e.g., “Aged 65 days.”

See: Dry Aged

AGED BEEF:

The beef products (carcass or cuts) are maintained in a fresh unfrozen state for a minimum of 14 days from the day of slaughter. Aging claims made within the supply chain (e.g., prior to the point of sale at retail or food service) shall specify the minimum number of days aged and the type of aging used on the principal display panel on the label (e.g., “Wet aged for a minimum of ____ days.”). If an aging claim is made at the point of sale to the consumer, the minimum claimed for aging shall appear on the principal display panel of the label (e.g., “Aged for a minimum of a minimum of ____ days.”).

For additional information refer to USDA, AMS, Standardization Branch

“ALL”, “PURE”, AND “100 PERCENT” POULTRY:

A labeling claim, such as, “meat used is 100 percent white meat”, may only be used when the poultry meat contains no added ingredients. A labeling claim, such as, “white meat only,” is acceptable when white meat is used to the exclusion of dark meat. In this situation, other ingredients may be present in the poultry portion of the product.

Starch and Gelatinized Wheat Starch”, “Pork and Binder Product with Barbecue Sauce”, or “BBQ Cooked Beef and Binder Product” followed by a parenthetical list of all of its ingredients. Bone-in red meat products do not have to comply with Federal meat regulation, 9 CFR 319.312 or 319.80 with regard to cooking yield and must indicate the presence of bones in product name, e.g., “Seasoned Cooked Pork Ribs with Barbecue Sauce” or “Barbecue Beef Ribs.”

When bone-in red meat products are injected, massaged, tumbled, etc., and do not return to green weight after cooking, the containing statement shall appear once on the label in (1) the ingredients statement as part of the red meat component (only if there is enough Beef Ribs without solution to meet the requirement for “Beef Ribs and BBQ Sauce”), or (2) in the product name, e.g., “Beef Ribs, containing 10 percent of a solution and BBQ Sauce.”

BARBECUE (Infrared Cooked):

The label must indicate heat source, e.g., “infrared cooked,” with lettering no less than one-half the size of the largest letter in the word “barbecue.”

BARBECUE MEAT OR POULTRY “EASTERN NORTH CAROLINE STYLE”:

Acceptable identification for a product that is enhanced in a vinegar based solution, apple or white. The solution is seasoned with pepper, i.e., black pepper, red pepper, or cayenne pepper. Other ingredients may include salt, sugar and hot pepper sauce.

BARBECUE SAUCE WITH CHICKEN:

The product must contain at least 15 percent cooked chicken meat. Changing the size of the term “Chicken” does not change the 15 percent cooked chicken meat requirement.

BARBECUE SAUCE WITH MEAT:

The product must contain at least 35 percent cooked meat. When the name of the product shows meat in smaller letters, not more than one-half the size of the largest letter in the product name, 25 percent cooked meat is required.

BEEF A LA KING:

The product must contain at least 20 percent cooked beef.

BEEF A LA MODE:

A product consisting of sliced beef (marinated in wine, cognac, vegetable stock) with carrots, onions, and other ingredients covered with wine sauce. The product must contain at least 50 percent beef.

BEEF ALMONDINE WITH VEGETABLES:

The product must contain at least 18 percent cooked meat on the ready-to-serve basis. The product must contain almonds.

BEEF AND DUMPLINGS WITH GRAVY:

The product must contain at least 25 percent meat and not more than 25 percent water blanching dry dumplings.

BEEF AND GRAVY:

The product contains at least 50 percent cooked beef.

See: **Gravy and Beef**

BEEF BLOOD:

This is an acceptable ingredient for beef patties provided the product name is qualified, such as "Beef and Blood Patties" or "Beef Patties with Blood."

BEEF BLOOD GLAZE:

A coating of beef blood is permitted on cured products (e.g., ham, hamette, etc.) if the product name is prominently qualified to reflect the coating. Nitrite is not permitted in the glaze.

BEEF BRISKET (Canned):

The minimum brine concentration required is 5.5 percent.

BEEF BURGUNDY OR BOURGUIGNONNE:

The product must contain at least 50 percent beef. Product contains beef cubes, mushrooms, onions, and red wine or burgundy gravy. May include other vegetables, e.g., carrots, shallots, tomato paste, or potatoes. Other acceptable names include "Beouf A La Bourguignonne," "Beef Burgundy Style," "Beef Burgundy," and "Burgundy Beef."

BEEF BURGUNDY WITH NOODLES:

The product must contain at least 50 percent beef in the beef burgundy portion. Total product should not contain more than 50 percent cooked noodles.

BEEF CHEEK MEAT AND BEEF HEAD MEAT AND PORK CHEEK MEAT AND PORK HEAD MEAT (USE AND LABELING AS AN INGREDIENT IN MEAT FOOD PRODUCTS):

Beef cheek meat and pork cheek meat refers to beef and pork cheeks from which the glandular material has been removed.

Beef head meat and pork head meat refer to muscle tissue remaining on the beef and hog skull after removal of the skin, cheeks, tongue, and lips. The meat normally attached to and considered as part of the tongue trimmings when detached from the tongue trimmings may also be included as beef head meat or pork head meat although it can be labeled as "beef" or "pork."

When beef cheek meat and/or beef head meat are included in boneless beef, its presence must be specifically declared. Examples include: "Boneless Beef - Contains Beef Cheek Meat and Beef Head Meat," "Boneless Beef Head Meat," "Boneless Beef - Ingredients: Beef, Beef Head Meat, Beef Cheek Meat," or "Boneless Beef - 20 percent Beef Head Meat, 15 percent Beef Cheek Meat."

Beef cheek meat and/or beef head meat may be used in unlimited quantities and identified as "beef" in meat food products unless restricted by regulatory standards for specific products as indicated in 9 CFR 319.15(a) (Chopped beef, ground beef), 319.15(b) (Hamburger), 319.15(d) (Fabricated steak), 319.81 (Roast Beef parboiled and steam roasted), 319.100 (Corned beef), 319.300 (Chili con carne), 319.301 (Chili con carne with beans), and 319.303 (Corned beef hash).

The presence of pork head meat is not required to be identified on the labeling of boneless pork. However, pork cheek meat and/or pork head meat may be used in unlimited quantities and identified as "pork" in meat food products, unless restricted by regulatory standards as indicated in 9 CFR 319.300 (Chili con carne) and 319.301 (Chili con carne with beans).

See: Policy Memo 098B dated August 1, 1990 - Cheek Meat

BEEF CONCENTRATE AND SALT:

Broth derived from cooking fresh beef containing 3 percent to 4 percent solids is centrifuged and evaporated to approximately 60 percent solids under vacuum. The water fraction is salted to a level of 25.5 percent of the water weight (100 lbs. concentrated stock at 60 percent will have 10.2 lbs. of salt added, making a total weight of 110.2 lbs.). There is no need for refrigeration.

BEEF CONSOMME:

The standard requires beef as an ingredient and a minimum protein content of at least 3 percent in the finished product.

“Beef stock” or “beef broth” (or mixture of both) may be used to comprise the beef ingredient. Additional optional ingredients are gelatin, beef extract, tomato puree, hydrolyzed plant protein, and seasoning.

BEEF (Dried or Air Dried):

Product name is “Air Dried Beef” or “Dried Beef.” MPR 2.04:1. It is usually cured by rub and/or stitch pump followed by cover pickle for 4 to 8 weeks with several overhauls (turned over for the application of additional cure), then placed in smokehouse or drying chambers for 3 to 10 days.

BEEF FIBRIN:

This is a component mixture of beef fibrinogen and beef thrombin plasma protein used to bind pieces of meat or poultry together. It is limited to 10 percent.

1. If used from seven percent of ten percent, it must appear in the product name, e.g., “Bacon Wrapped Beef Tenderloin Steak Formed with Beef Fibrinogen and Thrombin.” Therefore, the smallest letter in the product name must be at least 1/3 size of the smallest letter in the product name.
2. If used at less than seven percent, it must be a product name qualifier, e.g., “Formed with Beef Fibrinogen and Thrombin.” As a product name qualifier, there is no size requirement, however, it must contiguous to the product name and be prominent and conspicuous. Additionally, the terms “Beef Fibrin” or “Fibrin” may be used in the product name as a qualifier and its components identified elsewhere on the principal display panel. In this situation, the terms “Beef Fibrin” or “Fibrin” and its components are linked to each other by means of asterisks. Acceptable terminology’s for the components are “Beef Fibrinogen and Thrombin Plasma Protein,” or “Beef Fibrinogen and Thrombin.”

BEEF GRAVY MIX:

The product must contain at least 15 percent dried beef.

BEEF MARSALA:

The product must contain at least 50 percent beef. Product contains beef cubes, Marsala wine sauce, and usually mushrooms and onions. White wine may be used, but it may not replace Marsala wine.

BEEF ORIENTAL OR ORIENTAL BEEF:

The product must contain at least 12 percent meat and oriental style vegetables and sauce. The label must show true product name, e.g., "Beef Oriental with Vegetables."

BEEF ROULADE:

The product must contain at least 50 percent cooked meat. Usually a thin strip of flank meat wrapped around vegetables and cooked.

BEEF SLICES A-LA-PIZZAIOLA:

The product must contain at least 50 percent cooked beef.

BEEF STROGANOFF:

A dish with a creamy sauce prepared with beef cut into narrow strips or cubes and sautéed. Product labeled "Beef Stroganoff" should be prepared with a formula, which includes at least 45 percent beef, or 30 percent cooked beef.

1. The product must contain at least 10 percent sour cream, or
2. 7.5 percent sour cream, and 5 percent wine, or
3. 9.5 percent whole milk, 2 percent sour cream, and 2 1/2 percent wine.

BEEF STROGANOFF WITH NOODLES:

Meat and sauce portion must meet the standard for Beef Stroganoff. Total product shall contain no more than 50 percent cooked noodles.

BEEF SUKIYAKI:

The product must contain at least 30 percent meat based on total product. Consists of thinly sliced beef and various vegetables cooked in a flavored beef stock. This is not a stew as the vegetables and components are mixed during the cooking process. Vegetables used with this food are celery, bean sprouts, leeks, onions, mushrooms, Chinese cabbage, carrots, spinach, water chestnuts, bamboo shoots, and bean curds.

BEEF TRIPE STEW:

There are two versions of this product. One is of Mexican origin and merchandised in association with the term "Menudo."

Corn is a prominent ingredient in its formula. The standard for an item of this nature requires that it contain not less than 33 percent beef tripe computed on the basis of the uncooked tripe in relation to total ingredients.

The second product is popular in Puerto Rico. It is referred to as "Mondungo." The product is made with 25 percent raw beef tripe. The remainder consists principally of potatoes, a squash with pumpkin-like appearance and flavor, and a native vegetable called "Tanier." When the vegetables are not distinguishable, this product can be labeled as "Dominican Style Mondungo."

BEEF WELLINGTON:

It is made with beef tenderloin that is roasted very rare. It is then spread with a liver pate, covered with pastry, and baked in a hot oven until pastry is brown. The product must contain at least 50 percent cooked meat and no more than 30 percent pastry.

Alternatively, mushroom duxelle is an acceptable substitute for liver pate, but a true descriptive product name is required, e.g., "beef tenderloin covered with mushroom duxelle and wrapped with pastry."

BEERWURST, BIERWURST:

A cooked smoked sausage. Same requirements as beef salami, with the exception that pork may be used.

BERLINER:

A cooked smoked sausage usually made from coarsely cut cured pork in large casings. When beef is used, it shall not exceed 50 percent of the meat block. Pork stomachs or beef tripe not permitted.

See: Policy Memo 048 dated May 18, 1982

BERLINER BLOOD SAUSAGE:

A cooked blood sausage containing diced bacon. After cooking it is dried and smoked. Ham fat, snouts, and lips are not permitted.

See: **Blood Sausage**

BIER SCHINKEN (GR):

The literal translation is "Beer Ham." If product is made of all pork, it may be labeled "Bier Schinken."

MARINE OIL:

Herring oil and other marine species oils found by FDA to be satisfactory may be combined with animal and mixture of animal and vegetable oils processed as meat food products. Labels will bear statements identifying the presence of such substances, e.g., a shortening consisting of 50 percent herring oil and the remainder equal amounts of animal and vegetable oils would be "Shortening, Prepared with Herring Oil, Animal and Vegetable Oils."

MARKING:

Labeling may consist of a combination of printing, stenciling, box dyes, etc. for large true containers and for shipping containers. Crayons are unacceptable for applying required labeling features except for figures indicating content quantity. Approval of official marks appearing in newspaper advertisements, billboards, etc. is not necessary; however, such marks may be reviewed locally before publication. Such markings should conform to the illustrations in the regulations and not be misleading.

"MAY CONTAIN" STATEMENTS:

The use of "may contain" or "and/or" labeling may be used in the ingredients statement's sublisting of sliced and/or diced products from various sources.

See: "Composite Ingredients Statement."

MEAT AND DRESSING:

Product must contain at least 50 percent cooked meat.

MEAT AND DRESSING WITH GRAVY:

Product must contain at least 30 percent cooked meat.

MEAT BASE:

A granular, paste-like product which is shelf-stable primarily because of its high salt content (30-40 percent).

1. Beef Base - 15 percent beef or 10.5 percent cooked beef
2. Pork Base - 15 percent pork or 10.5 percent cooked pork
3. Ham Base - 18 percent ham

MEAT BROTH OR MEAT STOCK:

MPR 135:1. Condensed 67:1

MEAT BYPRODUCTS:

Byproducts must be individually declared by species and specific name in the ingredients statement, e.g., Pork Liver, Beef Tripe, and Beef fat.

MEAT CASSEROLES:

Product must contain at least 25 percent meat or 18 percent cooked meat.

MEAT CURRY:

Product must contain at least 50 percent meat.

MEAT FLAVORING:

Meat flavoring – when characteristic meat flavorings such as bacon are added in amounts less than 2 percent in addition to the required meat component of a product, such meat flavorings need not appear in the product label.

MEAT FOLDOVER MIT DRESSING:

Product must contain at least 50 percent meat (chopped and formed).

MEAT FOOD PRODUCTS CONTAINING POULTRY INGREDIENTS - LABELING:

Meat food products containing poultry ingredients in amounts that exceed 20 percent of the total livestock and poultry product portion of the meat food product must have product names that indicate the presence of the poultry ingredients, e.g., “Beef and Chicken Chili” or “Chili made with Beef and Chicken.”

Meat food products containing poultry ingredients in amounts at 20 percent or less of the total livestock and poultry product portion of the meat food product must have product names that are qualified to indicate the presence of the poultry ingredients, e.g., “Beef Stew - Turkey Added.”

However, meat food products that do not meet specified minimum livestock ingredient requirements because poultry ingredients are replacing any part of the required livestock ingredients must have product names that indicate the presence of the poultry ingredients, e.g., “Beef and Turkey Stew” or “Stew Made with Beef and Turkey.”

This policy does not apply to: (1) red meat products that are expected to contain poultry ingredients, e.g., “Brunswick Stew and Potted Meat Food Product” (Section 9 CFR 319.761); (2) cooked sausages identified in Section 9 CFR 319.180 of the meat regulations (Policy Memo 005A); or (3) nonspecific loaves, rolls, logs, etc., e.g., Pickle and Pimento Loaf.

See: Policy Memo 030A dated September 13, 1982

MEAT LOAF:

Uncooked or cooked pork, beef, veal or lamb, and other ingredients in loaf form, but not canned.

1. Ingredients, e.g., cracker meal, oatmeal, bread crumbs, nonfat dry milk, soy ingredients (untextured), milk, and whole eggs are not required in the product name.

2. Product may contain:

a. Head meat, cheek meat, heart meat, and tongue meat under label declaration in the ingredients statement only.

b. Not more than 12 percent extenders and binders.

c. Partially defatted chopped beef or pork up to 25 percent and declared as meat in the ingredients statement.

3. Product must contain at least 65 percent meat.

4. Onion, tomato juice, water, and other liquid extenders are not directly controlled.

MEAT LOAF, CANNED (Perishable):

Canned perishable products in the loaf category must:

1. Meet the perishable labeling requirements. See: 9 CFR 317.2(k),

2. Be cured with at least 1 ounce nitrate per 100 pounds of product and 1/2 percent dextrose or 1 percent sugar.

3. Have a brine concentration of at least 3.5 percent in the finished product. Products that contain cereal, starch, or other extenders must have a brine concentration of at least 6.1 percent.

MEAT LOAF, CANNED (Sterile Packed):

No head, cheek, heart, or tongue meat permitted. Other requirements are the same as uncanned cured meat loaf. Binders and extenders must be shown in the product name, e.g., "Meat Loaf, cereal added."

MEAT PASTY OR PASTIES:

Product must contain at least 25 percent meat. The label must show the true product name, e.g., "Beef Pasty."

MEAT PIE FILLING:

Product must contain at least 37 percent meat.

MEAT PIES (OR VEGETABLE MEAT PIES):

Product must contain 25 percent meat; meat in gravy may be counted towards meat content.

MEAT/POULTRY EXTENDED PRODUCTS:

These should always be listed in the ingredients statement of the secondary product by their correct name, e.g., "Beef, water and binder product," unless it is included in the name of the product, e.g., "Chili made with beef and binder product."

MEAT RAVIOLI:

Product must contain at least 10 percent meat in ravioli.

MEAT RAVIOLI IN MEAT SAUCE:

Product must contain at least 10 percent meat in ravioli and at least 50 percent ravioli in total product, and at least 6 percent meat in sauce.

MEAT RAVIOLI IN SAUCE:

Product must contain at least 10 percent meat in the ravioli and at least 50 percent ravioli in the total product.

MEAT SAUCE:

Product must contain at least 6 percent ground meat.

MEAT SPREADS:

Product must contain at least 50 percent meat or 35 percent cooked meat. When another major component is considered a significant source of protein such as cheese is added the requirement is reduced to 25 percent cooked meat. Product must show a true product name, e.g., "Sausage and Cheese Spread."

MEAT STICK AND CHEESE COMBINATION PRODUCTS:

The following criteria are used for dry meat stick and cheese combination products that need not bear a “keep refrigerated” handling statement.

- (1) The dry meat stick portion must have a water activity of less than 0.90, the cheese portion must have a water activity of less than 0.94, and the equilibrium of the water activity of the two components must be no greater than 0.92;
- (2) the dry meat portion, if fermented, must be fermented by an active fermentation culture (typically to a pH 5.0 or below) and;
- (3) for products where the meat portion and the cheese portion are packaged together, there must be a heat seal between the dry meat stick and cheese components which separates the meat stick from the cheese stick by at least 4 mm.
- (4) Dry meat stick and cheese combination products not meeting these criteria must be labeled with a “keep refrigerated” statement in lieu of compelling data that establish safety.

Products not meeting the criteria stated above can be labeled without a “keep refrigerated” statement if a control program ensuring safety and shelf stability is established by the established.

MEATBALL STEW:

Meatball stew contains at least 25 percent meatballs and usually contains vegetables such as potatoes, peas, carrots, etc., and gravy or thick broth resulting from cooking all ingredients together. The meatballs must meet the Meatball Standard.

MEATBALLS:

Uncooked or cooked pork, beef, veal, and lamb, and other ingredients in a ball form.

1. Product must contain at least 65 percent meat.
2. Binders and extenders are limited to 12 percent of the total product. 6.8 percent of isolated soy protein is considered the equivalent to 12 percent of the other binders or extenders. The permitted binders and extenders include, but are not limited to, cereal, bread crumbs, cracker meal, soy flour, soy protein concentrate, isolated soy protein, and textured vegetable protein.
3. Cheeks, hearts, and tongues are not allowed, but product may contain head meat, cheek meat, heart meat, and tongue meat when declared in the ingredients statement.

4. Partially defatted chopped (PDC) (species) may be used up to 25 percent of the meat block. PDC (species) can be identified as (species) in the ingredients statements. (See entry for Partially Defatted Chopped (species)).

MEATBALLS IN SAUCE:

Requires a 50 percent minimum of meat-balls, by weight in finished product.

MEATBALLS, SWEDISH STYLE:

Product must contain at least 65 percent fresh meat. "Swedish Meatballs" or "Swedish Style Meatballs" are small in size and usually contain two or three different varieties of meat, nutmeg and/or allspice, potatoes, and milk. "Swedish Brand Meatballs Made in USA" means any meatball.

MEATBALLS, TURKEY:

Product must contain at least 65 percent raw turkey meat. Skin is permitted in natural proportions of meat used, if skin is in excess of natural proportions, it shall be reflected in the product name.

MEDITERRANEAN STYLE:

Acceptable identification for product containing onion or garlic, olive oil and four of any of the following groups:

1. Vegetable or fruit: dried apricot, artichoke, dried date, dried fig, eggplant, tomato, pepper (green or red), squash, lemon or lemon juice, raisin and olives.
2. Legume or nut: fava bean, chick pea, white cannelloni bean, green bean, lentil, almond, pine nut, pistachio.
3. Seasoning: dill, coriander, cinnamon, cumin, fennel, basil, oregano, thyme, saffron, rosemary, parsley, mint, sumac, turmeric.
4. A regional dish as component, e.g., pita bread, yogurt, Italian or Greek type cheese, pasta, couscous or bulgur.

MERGUEZ, MERGUES OR MERGHEZ SAUSAGE:

A hot and spicy fresh sausage originating in North Africa and common in France which contains hot pepper and/or paprika. The meat component must contain beef and may contain lamb or mutton when labeled as "Merguez Sausage." When pork is used as part of meat component, the product is labeled as "Merguez Sausage with Pork." When pork is the only meat ingredient, the product is labeled "Pork Merguez Sausage."

METTWURST:

Exhibit 3

Hampton Creek Foods 8/12/15



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER AUG 12, 2015

VIA OVERNIGHT MAIL

Mr. Joshua Tetrick, Founder and Chief Executive Officer
Hampton Creek Foods, Inc.
371 Tenth Street
San Francisco, CA 94193

Re: 470327

Dear Mr. Tetrick,

The U.S. Food and Drug Administration (FDA) reviewed the labels and website labeling for your Just Mayo and Just Mayo Sriracha products in June, 2015. The label for these products directs the consumer to your website at the Internet address www.hamptoncreek.com (<http://www.hamptoncreek.com/>). We examined your website in June, 2015. Based on our review, we have concluded that these products are in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343] and its implementing regulations found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links on FDA's home page at <http://www.fda.gov> (<http://www.fda.gov/>).

The significant violations are as follows:

1. Your Just Mayo and Just Mayo Sriracha products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the labeling for these products bears nutrient content claims, but the products do not meet the requirements to make such claims.

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation authorizing the use of such a claim. Characterizing the level of a nutrient on the food labeling of a product without complying with the specific requirements pertaining to the nutrient content claim for that nutrient misbrands the product under section 403(r)(1)(A) of the Act. Specifically, the "cholesterol free" claim on your regular Just Mayo product label does not meet the requirements for a cholesterol free claim in accordance with 21 CFR 101.62(d). Additionally, your website,

www.hamptoncreek.com, includes the statement "You'll never find cholesterol in our products" (in reference to all of your products, including your Just Mayo and Just Mayo Sriracha products), which is an unauthorized synonym for "cholesterol free." However, even if the claim were an authorized synonym for "cholesterol free," the claim does not meet the requirements for a cholesterol free claim in accordance with 21 CFR 101.62(d) when referring to your Just Mayo and Just Mayo Sriracha products.

In accordance with the requirements in 21 CFR 101.62(d)(ii)(D), if the reference amount customarily consumed (RACC) is small (30 grams or less or 2 tablespoons or less) and the food contains more than 13 grams of total fat per 50 grams, then the label or labeling must disclose the level of total fat in a serving of the product in immediate proximity to the cholesterol claim. The RACC for your Just Mayo product and Just Mayo Sriracha product is 15 grams. According to the nutrition labels for these products, both of these products contain 10 grams of total fat per 14 gram serving. Based on this, the level of total fat in 50 grams of these products is approximately 36 grams; therefore, the labeling must include a statement that discloses the level of total fat in a serving of the product in immediate proximity to the cholesterol claims. However, the label for your Just Mayo product and the labeling for you Just Mayo and Just Mayo Sriracha products do not bear a statement disclosing the level of total fat in a serving of the products in immediate proximity to the claims.

2. Your Just Mayo and Just Mayo Sriracha products are misbranded within the meaning of section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because the website labeling at www.hamptoncreek.com, which is referenced on the product labels, includes an unauthorized health claim.

Specifically, your website, www.hamptoncreek.com includes the following statements, "Your Heart Matters. When your heart is healthy, well, we're happy. You'll never find cholesterol in our products." Adjacent to this statement is a heart shaped symbol with a smiling face. Together these statements and heart symbol are an implied health claim that these products can reduce the risk of heart disease due to the absence of cholesterol.

While there are authorized health claims about cholesterol and the reduced risk of heart disease⁽¹¹⁾, these products do not qualify to make these health claims, in part, due to the amount of fat that they contain. FDA's regulation at 21 CFR 101.14(a)(4) disqualifies foods from making health claims that contain more than 13 grams of fat per RACC; per labeled serving; or per 50 grams (if the RACC is less than 30 grams). As previously noted, your regular Just Mayo product contains 36 grams of fat per 50 grams. In addition, the Sriracha Just Mayo product also contains 36 grams of fat per 50 gram serving. Therefore, neither product qualifies to make a health claim as described under 21 CFR 101.14(a)(4).

3. Your Just Mayo and Just Mayo Sriracha products are misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that they purport to be the standardized food mayonnaise due to the misleading name and imagery used on the label, but do not qualify as the standardized food mayonnaise as described under 21 CFR 169.140. The name "Just Mayo" and an image of an egg are prominently featured on the labels for these products. The term "mayo" has long been used and understood as shorthand or slang for mayonnaise. The use of the term "mayo" in the product names and the image of an egg may be misleading to consumers because it may lead them to believe that the products are the standardized food, mayonnaise, which must contain eggs as described under 21 CFR 169.140(c). Additionally, the use of the term "Just" together with "Mayo" reinforces the impression that the products are real mayonnaise by suggesting that they are "all mayonnaise" or "nothing but" mayonnaise. However, your Just Mayo and Just Mayo Sriracha do not meet the definition of the standard for mayonnaise. According to the labels for these products, neither product contains eggs. Additionally, the products contain additional ingredients that are not permitted by the standard of identity for mayonnaise, such as modified food starch.

4. Your Just Mayo and Just Mayo Sriracha products are misbranded within the meaning of section 403(g) of the Act [21 U.S.C. § 343(g)] in that they purport to be a food for which a definition and standard of identity has been

prescribed by regulation, but they fail to conform to such definition and standard. Specifically, these products purport to be mayonnaise by prominently featuring the word "Mayo" on the labels, which has long been used to refer to mayonnaise. Mayonnaise is a food for which a definition and standard of identity has been prescribed by regulation (see 21 CFR 169.140). According to the standard of identity for mayonnaise, egg is a required ingredient (21 CFR 169.140(c)); however, based on the ingredient information on the labels, these products do not contain eggs. We also note that these products contain additional ingredients that are not permitted by the standard, such as modified food starch, pea protein, and beta-carotene, which may be used to impart color simulating egg yolk. Therefore, these products do not conform to the standard for mayonnaise.

The above violations are not meant to be an all-inclusive list of violations that may exist in connection with your products or their labeling. It is your responsibility to ensure that your products comply with the Act and its implementing regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

In addition, we offer the following comments:

- The statement of the place of business must include the street address unless it is shown in a current city directory or telephone directory (see 21 CFR 101.5(d)).
- The nutrition labels do not meet the requirements in 21 CFR 101.9. We provide the following examples:
 - o The heading "Nutrition Facts" does not meet the requirements in 21 CFR 101.9(d)(2).
 - o The nutrition labels are not enclosed in a box as required in 21 CFR 101.9 (d)(1)(i).
 - o The nutrition labels do not include the full footnote required in 21 CFR 101.9(d)(9).
- The information panel on the regular Just Mayo product does not meet the requirements in 21 CFR 101.2(a) because it is not placed on the part of the label immediately contiguous and to the right of the principal display panel.

You should respond in writing within 15 working days from receipt of this letter. Your response should outline the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent their recurrence. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the corrections.

You should direct your written reply to Anam Drumheller, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions regarding this letter, you may contact Ms. Drumheller via email at anam.drumheller@fda.hhs.gov (<mailto:anam.drumheller@fda.hhs.gov>).

Sincerely,

/S/

William A. Correll, Jr.

Director

Office of Compliance

Center for Food Safety

and Applied Nutrition

cc: FDA San Francisco District

¹³¹ See 21 CFR 101.75 and the FDA Modernization Act (FDAMA) health claim, "Saturated Fat, Cholesterol, and Trans Fat, and Reduced Risk of Heart Disease," (Docket No. 2006Q-0458) at <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073621.htm>.

Close Out Letter

- Hampton Creek Foods - Close Out Letter 12/18/15
([/ICECI/EnforcementActions/WarningLetters/2015/ucm478309.htm](http://ICECI/EnforcementActions/WarningLetters/2015/ucm478309.htm))

More in 2015
([/ICECI/EnforcementActions/WarningLetters/2015/default.htm](http://ICECI/EnforcementActions/WarningLetters/2015/default.htm))

BUSINESS DAY

F.D.A. Allows Maker of Just Mayo to Keep Product's Name

By STEPHANIE STROM DEC. 17, 2015

Sometimes, semantics can make a difference.

Hampton Creek, a food company that makes plant-based egg substitutes, said on Thursday that the Food and Drug Administration had reversed course and would allow it to continue using the name Just Mayo for an eggless spread that has come under attack from large food companies and the trade association for egg producers.

Federal standards require that any product called mayonnaise contain eggs, which neither Just Mayo nor Just Mayo Sriracha, a derivative product, do. Initially, the F.D.A., which oversees food labeling, had warned Hampton Creek in August that the name Just Mayo and the product's logo, an egg "cracked" by a young pea plant, might mislead consumers into thinking that the product contained actual eggs.

Now, the agency has decided that Hampton Creek can keep the Just Mayo name and its logo — as long as it makes changes in its label. The company will use bigger type on the front of the label for the list of product attributes like "egg-free." And, the label will define the word "just" in the brand name to mean "guided by reason, justice and fairness" instead of suggesting that it was an exact replica of mayonnaise.

The agency's original decision had come after Unilever, the giant food company that produces and markets Hellmann's mayonnaise (known as Best Foods mayonnaise west of the Rockies) sued Hampton Creek. Unilever dropped the suit just weeks after filing it — but months later, the F.D.A. raised similar issues.

That raised the possibility that Hampton Creek's branding might have to change, which would have been a crippling blow to what is still a small though rapidly growing start-up.

"This gives us the chance to tell the bigger story about what we're trying to accomplish with Hampton Creek in terms of changing the food system," said Josh Tetrick, Hampton Creek's founder and chief executive. "I'm really positive about this outcome."

In a statement, the F.D.A. said that the company had promised to make changes to its labeling that would ensure it was truthful and not misleading. "Therefore, the F.D.A. considers the issues cited in the warning letter to be resolved and will issue a closeout letter soon," the agency said.

Mr. Tetrick said he had been pleasantly surprised by his meetings with regulators. "About two months ago, I went there and sat down with them," he said. "Before that, the F.D.A. seemed to me a sort of abstraction, but then you go there and it's a building with people inside, human beings who are thoughtful and engaging and really seemed to be trying to hear us out."

Mr. Tetrick said Hampton Creek, which is backed by venture capitalists, had placed an order for the new labels Thursday morning and consumers would start seeing them on the shelves in stores like Target, Walmart and Whole Foods in about 60 days.

A version of this article appears in print on December 18, 2015, on Page B2 of the New York edition with the headline: F.D.A. Allows Maker of Just Mayo to Keep Product's Name.

Exhibit 4



FEDERAL TRADE COMMISSION PROTECTING AMERICA'S CONSUMERS

Truth In Advertising

When consumers see or hear an advertisement, whether it's on the Internet, radio or television, or anywhere else, federal law says that ad must be truthful, not misleading, and, when appropriate, backed by scientific evidence. The Federal Trade Commission enforces these truth-in-advertising laws, and it applies the same standards no matter where an ad appears – in newspapers and magazines, online, in the mail, or on billboards or buses. The FTC looks especially closely at advertising claims that can affect consumers' health or their pocketbooks – claims about food, over-the-counter drugs, dietary supplements, alcohol, and tobacco and on conduct related to high-tech products and the Internet. The FTC also monitors and writes reports about ad industry practices regarding the marketing of alcohol and tobacco.

When the FTC finds a case of fraud perpetrated on consumers, the agency files actions in federal district court for immediate and permanent orders to stop scams; prevent fraudsters from perpetrating scams in the future; freeze their assets; and get compensation for victims.

[Protecting Consumers from Fraud and Deception](#)

[Environmentally Friendly Products: FTC's Green Guides](#)

[The FTC's Endorsement Guides: Being Up-Front With Consumers](#)

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FTC Policy Statement on Deception

DATE: October 14, 1983

Appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984).

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter responds to the Committee's inquiry regarding the Commission's enforcement policy against deceptive acts or practices.¹ We also hope this letter will provide guidance to the public.

Section 5 of the FTC Act declares unfair or deceptive acts or practices unlawful. Section 12 specifically prohibits false ads likely to induce the purchase of food, drugs, devices or cosmetics. Section 15 defines a false ad for purposes of Section 12 as one which is "misleading in a material respect."² Numerous Commission and judicial decisions have defined and elaborated on the phrase "deceptive acts or practices" under both Sections 5 and 12. Nowhere, however, is there a single definitive statement of the Commission's view of its authority. The Commission believes that such a statement would be useful to the public, as well as the Committee in its continuing review of our jurisdiction.

We have therefore reviewed the decided cases to synthesize the most important principles of general applicability. We have attempted to provide a concrete indication of the manner in which the Commission will enforce its deception mandate. In so doing, we intend to address the concerns that have been raised about the meaning of deception, and thereby attempt to provide a greater sense of certainty as to how the concept will be applied.³

I. SUMMARY

Certain elements undergird all deception cases. *First*, there must be a representation, omission or practice that is likely to mislead the consumer.⁴ Practices that have been found misleading or deceptive in specific cases include false oral or written representations, misleading price claims, sales of hazardous or systematically defective products or services without adequate disclosures, failure to disclose information regarding pyramid sales, use of bait and switch techniques, failure to perform promised services, and failure to meet warranty obligations.⁵

Second, we examine the practice from the perspective of a consumer acting reasonably in the circumstances. If the representation or practice affects or is directed primarily to a particular group, the Commission examines reasonableness from the perspective of that group.

Third, the representation, omission, or practice must be a "material" one. The basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service. If so, the practice is material, and consumer injury is likely, because consumers are likely to have chosen differently but for the deception. In many instances,

materiality, and hence injury, can be presumed from the nature of the practice. In other instances, evidence of materiality may be necessary.

Thus, the Commission will find deception if there is a representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment. We discuss each of these elements below.

II. THERE MUST BE A REPRESENTATION, OMISSION, OR PRACTICE THAT IS LIKELY TO MISLEAD THE CONSUMER.

Most deception involves written or oral misrepresentations, or omissions of material information. Deception may also occur in other forms of conduct associated with a sales transaction. The entire advertisement, transaction or course of dealing will be considered. The issue is whether the act or practice is likely to mislead, rather than whether it causes actual deception.⁶

Of course, the Commission must find that a representation, omission, or practice occurred. In cases of express claims, the representation itself establishes the meaning. In cases of implied claims, the Commission will often be able to determine meaning through an examination of the representation itself, including an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction.⁷ In other situations, the Commission will require extrinsic evidence that reasonable consumers reach the implied claims.⁸ In all instances, the Commission will carefully consider any extrinsic evidence that is introduced.

Some cases involve omission of material information, the disclosure of which is necessary to prevent the claim, practice, or sale from being misleading.⁹ Information may be omitted from written¹⁰ or oral¹¹ representations or from the commercial transaction.¹²

In some circumstances, the Commission can presume that consumers are likely to reach false beliefs about the product or service because of an omission. At other times, however, the Commission may require evidence on consumers' expectations.¹³

Marketing and point-of-sales practices that are likely to mislead consumers are also deceptive. For instance, in bait and switch cases, a violation occurs when the offer to sell the product is not a bona fide offer.¹⁴ The Commission has also found deception where a sales representative misrepresented the purpose of the initial contact with customers.¹⁵ When a product is sold, there is an implied representation that the product is fit for the purposes for which it is sold. When it is not, deception occurs.¹⁶ There may be a concern about the way a product or service is marketed, such as where inaccurate or incomplete information is provided.¹⁷ A failure to perform services promised under a warranty or by contract can also be deceptive.¹⁸

III. THE ACT OR PRACTICE MUST BE CONSIDERED FROM THE PERSPECTIVE OF THE REASONABLE CONSUMER

The Commission believes that to be deceptive the representation, omission or practice must be likely to mislead reasonable consumers under the circumstances.¹⁹ The test is whether the consumer's interpretation or reaction is reasonable.²⁰ When representations or sales practices are targeted to a specific audience, the Commission determines the effect of the practice on a

reasonable member of that group. In evaluating a particular practice, the Commission considers the totality of the practice in determining how reasonable consumers are likely to respond.

A company is not liable for every interpretation or action by a consumer. In an advertising context, this principle has been well-stated:

An advertiser cannot be charged with liability with respect to every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded. Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim. Perhaps a few misguided souls believe, for example, that all "Danish pastry" is made in Denmark. Is it therefore an actionable deception to advertise "Danish pastry" when it is made in this country.? Of course not, A representation does not become "false and deceptive" merely because it will be unreasonably misunderstood by an insignificant and unrepresentative segment of the class of persons to whom the representation is addressed. Heinz W. Kirchner, 63 F.T.C. 1282, 1290 (1963).

To be considered reasonable, the interpretation or reaction does not have to be the only one.²¹ When a seller's representation conveys more than one meaning to reasonable consumers, one of which is false, the seller is liable for the misleading interpretation.²² An interpretation will be presumed reasonable if it is the one the respondent intended to convey.

The Commission has used this standard in its past decisions. "...The test applied by the Commission is whether the interpretation is reasonable in light of the claim."²³ In the Listerine case, the Commission evaluated the claim from the perspective of the "average listener."²⁴ In a case involving the sale of encyclopedias, the Commission observed "[i]n determining the meaning of an advertisement, a piece of promotional material or a sales presentation, the important criterion is the net impression that it is likely to make on the general populace."²⁵ The decisions in *American Home Products*, *Bristol Myers*, and *Sterling Drug* are replete with references to reasonable consumer interpretations.²⁶ In a land sales case, the Commission evaluated the oral statements and written representations "in light of the sophistication and understanding of the persons to whom they were directed."²⁷ Omission cases are no different: the Commission examines the failure to disclose in light of expectations and understandings of the typical buyer²⁸ regarding the claims made.

When representations or sales practices are targeted to a specific audience, such as children, the elderly, or the terminally ill, the Commission determines the effect of the practice on a reasonable member of that group.²⁹ For instance, if a company markets a cure to the terminally ill, the practice will be evaluated from the perspective of how it affects the ordinary member of that group. Thus, terminally ill consumers might be particularly susceptible to exaggerated cure claims. By the same token, a practice or representation directed to a well-educated group, such as a prescription drug advertisement to doctors, would be judged in light of the knowledge and sophistication of that group.³⁰

As it has in the past, the Commission will evaluate the entire advertisement, transaction, or course of dealing in determining how reasonable consumers are likely to respond. Thus, in

advertising the Commission will examine "the entire mosaic, rather than each tile separately."³¹ As explained by a court of appeals in a recent case:

The Commission's right to scrutinize the visual and aural imagery of advertisements follows from the principle that the Commission looks to the impression made by the advertisements as a whole. Without this mode of examination, the Commission would have limited recourse against crafty advertisers whose deceptive messages were conveyed by means other than, or in addition to, spoken words. *American Home Products*, 695 F.2d 681, 688 (3d Cir. Dec. 3, 1982).³²

Commission cases reveal specific guidelines. Depending on the circumstances, accurate information in the text may not remedy a false headline because reasonable consumers may glance only at the headline.³³ Written disclosures or fine print may be insufficient to correct a misleading representation.³⁴ Other practices of the company may direct consumers' attention away from the qualifying disclosures.³⁵ Oral statements, label disclosures or point-of-sale material will not necessarily correct a deceptive representation or omission.³⁶ Thus, when the first contact between a seller and a buyer occurs through a deceptive practice, the law may be violated even if the truth is subsequently made known to the purchaser.³⁷ Pro forma statements or disclaimers may not cure otherwise deceptive messages or practices.³⁸

Qualifying disclosures must be legible and understandable. In evaluating such disclosures, the Commission recognizes that in many circumstances, reasonable consumers do not read the entirety of an ad or are directed away from the importance of the qualifying phrase by the acts or statements of the seller. Disclosures that conform to the Commission's Statement of Enforcement Policy regarding clear and conspicuous disclosures, which applies to television advertising, are generally adequate, *CCH Trade Regulation Reporter*, ¶ 7569.09 (Oct. 21, 1970). Less elaborate disclosures may also suffice.³⁹

Certain practices, however, are unlikely to deceive consumers acting reasonably. Thus, the Commission generally will not bring advertising cases based on subjective claims (taste, feel, appearance, smell) or on correctly stated opinion claims if consumers understand the source and limitations of the opinion.⁴⁰ Claims phrased as opinions are actionable, however, if they are not honestly held, if they misrepresent the qualifications of the holder or the basis of his opinion or if the recipient reasonably interprets them as implied statements of fact.⁴¹

The Commission generally will not pursue cases involving obviously exaggerated or puffing representations, *i.e.*, those that the ordinary consumers do not take seriously.⁴² Some exaggerated claims, however, may be taken seriously by consumers and are actionable. For instance, in rejecting a respondent's argument that use of the words "electronic miracle" to describe a television antenna was puffery, the Commission stated:

Although not insensitive to respondent's concern that the term miracle is commonly used in situations short of changing water into wine, we must conclude that the use of "electronic miracle" in the context of respondent's grossly exaggerated claims would lead consumers to give added credence to the overall suggestion that this device is superior to other types of antennae. *Jay Norris*, 91 F.T.C. 751, 847 n.20 (1978), *aff'd*, 598 F.2d 1244 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979).

Finally, as a matter of policy, when consumers can easily evaluate the product or service, it is inexpensive, and it is frequently purchased, the Commission will examine the practice closely before issuing a complaint based on deception. There is little incentive for sellers to misrepresent (either by an explicit false statement or a deliberate false implied statement) in these circumstances since they normally would seek to encourage repeat purchases. Where, as here, market incentives place strong constraints on the likelihood of deception, the Commission will examine a practice closely before proceeding.

In sum, the Commission will consider many factors in determining the reaction of the ordinary consumer to a claim or practice. As would any trier of fact, the Commission will evaluate the totality of the ad or the practice and ask questions such as: how clear is the representation? how conspicuous is any qualifying information? how important is the omitted information? do other sources for the omitted information exist? how familiar is the public with the product or service?⁴³

IV. THE REPRESENTATION, OMISSION OR PRACTICE MUST BE MATERIAL

The third element of deception is materiality. That is, a representation, omission or practice must be a material one for deception to occur.⁴⁴ A "material" misrepresentation or practice is one which is likely to affect a consumer's choice of or conduct regarding a product.⁴⁵ In other words, it is information that is important to consumers. If inaccurate or omitted information is material, injury is likely.⁴⁶

The Commission considers certain categories of information presumptively material.⁴⁷ First, the Commission presumes that express claims are material.⁴⁸ As the Supreme Court stated recently, "[i]n the absence of factors that would distort the decision to advertise, we may assume that the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising."⁴⁹ Where the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false, materiality will be presumed because the manufacturer intended the information or omission to have an effect.⁵⁰ Similarly, when evidence exists that a seller intended to make an implied claim, the Commission will infer materiality.⁵¹

The Commission also considers claims or omissions material if they significantly involve health, safety, or other areas with which the reasonable consumer would be concerned. Depending on the facts, information pertaining to the central characteristics of the product or service will be presumed material. Information has been found material where it concerns the purpose,⁵² safety,⁵³ efficacy,⁵⁴ or cost,⁵⁵ of the product or service. Information is also likely to be material if it concerns durability, performance, warranties or quality. Information pertaining to a finding by another agency regarding the product may also be material.⁵⁶

Where the Commission cannot find materiality based on the above analysis, the Commission may require evidence that the claim or omission is likely to be considered important by consumers. This evidence can be the fact that the product or service with the feature represented costs more than an otherwise comparable product without the feature, a reliable survey of consumers, or credible testimony.⁵⁷

A finding of materiality is also a finding that injury is likely to exist because of the representation, omission, sales practice, or marketing technique. Injury to consumers can take many forms.⁵⁸ Injury exists if consumers would have chosen differently but for the deception. If different choices are likely, the claim is material, and injury is likely as well. Thus, injury and materiality are different names for the same concept.

V. CONCLUSION

The Commission will find an act or practice deceptive if there is a misrepresentation, omission, or other practice, that misleads the consumer acting reasonably in the circumstances, to the consumer's detriment. The Commission will not generally require extrinsic evidence concerning the representations understood by reasonable consumers or the materiality of a challenged claim, but in some instances extrinsic evidence will be necessary.

The Commission intends to enforce the FTC Act vigorously. We will investigate, and prosecute where appropriate, acts or practices that are deceptive. We hope this letter will help provide you and the public with a greater sense of certainty concerning how the Commission will exercise its jurisdiction over deception. Please do not hesitate to call if we can be of any further assistance.

By direction of the Commission, Commissioners Pertschuk and Bailey dissenting, with separate statements attached and with separate response to the Committee's request for a legal analysis to follow.

/s/James C. Miller III
Chairman

cc: Honorable James T. Broyhill
Honorable James J. Florio
Honorable Norman F. Lent

ENDNOTES:

¹S. Rep. No. 97-451, 97th Cong., 2d Sess. 16; H.R. Rep. No. 98-156, Part I, 98th Cong., 1st Sess. 6 (1983). The Commission's enforcement policy against unfair acts or practices is set forth in a letter to Senators Ford and Danforth, dated December 17, 1980.

²In determining whether an ad is misleading, Section 15 requires that the Commission take into account "representations made or suggested" as well as "the extent to which the advertisement fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual." 15 U.S.C. 55. If an act or practice violates Section 12, it also violates Section 5. *Simeon Management Corp.*, 87 F.T.C. 1184, 1219 (1976), *aff'd*, 579 F.2d 1137 (9th Cir. 1978); *Porter & Dietsch*, 90 F.T.C. 770, 873-74 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980).

³Chairman Miller has proposed that Section 5 be amended to define deceptive acts. Hearing Before the Subcommittee for Consumers of the Committee on Commerce, Science, and Transportation, United States Senate, 97th Cong., 2d Sess. *FTCs Authority Over Deceptive*

Advertising, July 22, 1982, Serial No. 97-134, p. 9. Three Commissioners believe a legislative definition is unnecessary. *Id.* at 45 (Commissioner Clanton), at 51 (Commissioner Bailey) and at 76 (Commissioner Pertschuk). Commissioner Douglas supports a statutory definition of deception. Prepared statement by Commissioner George W. Douglas, Hearing Before the Subcommittee for Consumers of the Committee on Commerce, Science and Transportation, United States Senate, 98th Cong. 1st Sess. (March 16, 1983) p. 2.

⁴A misrepresentation is an express or implied statement contrary to fact. A misleading omission occurs when qualifying information necessary to prevent a practice, claim, representation, or reasonable expectation or belief from being misleading is not disclosed. Not all omissions are deceptive, even if providing the information would benefit consumers. As the Commission noted in rejecting a proposed requirement for nutrition disclosures, "In the final analysis, the question whether an advertisement requires affirmative disclosure would depend on the nature and extent of the nutritional claim made in the advertisement." *ITT Continental Baking Co. Inc.*, 83 F.T.C. 865, 965 (1976). In determining whether an omission is deceptive, the Commission will examine the overall impression created by a practice, claim, or representation. For example, the practice of offering a product for sale creates an implied representation that it is fit for the purposes for which it is sold. Failure to disclose that the product is not fit constitutes a deceptive omission. [See discussion below at 5-6] Omissions may also be deceptive where the representations made are not literally misleading, if those representations create a reasonable expectation or belief among consumers which is misleading, absent the omitted disclosure.

Non-deceptive emissions may still violate Section 5 if they are unfair. For instance, the R-Value Rule, 16 C.F.R. 460.5 (1983), establishes a specific method for testing insulation ability, and requires disclosure of the figure in advertising. The Statement of Basis and Purpose, 44 FR 50,242 (1979), refers to a deception theory to support disclosure requirements when certain misleading claims are made, but the rule's general disclosure requirement is based on an unfairness theory. Consumers could not reasonably avoid injury in selecting insulation because no standard method of measurement existed.

⁵Advertising that lacks a reasonable basis is also deceptive. *Firestone*, 81 F.T.C. 398, 451-52 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973). *National Dynamics*, 82 F.T.C. 488, 549-50 (1973); *aff'd and remanded on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974), *reissued*, 85 F.T.C. 391 (1976). *National Comm'n on Egg Nutrition*, 88 F.T.C. 89, 191 (1976), *aff'd*, 570 F.2d 157 (7th Cir.), *cert. denied*, 439 U.S. 821, *reissued*, 92 F.T.C. 848 (1978). The deception theory is based on the fact that most ads making objective claims imply, and many expressly state, that an advertiser has certain specific grounds for the claims. If the advertiser does not, the consumer is acting under a false impression. The consumer might have perceived the advertising differently had he or she known the advertiser had no basis for the claim. This letter does not address the nuances of the reasonable basis doctrine, which the Commission is currently reviewing. 48 FR 10,471 (March 11, 1983).

⁶In *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3d Cir. 1976), the court noted "the likelihood or propensity of deception is the criterion by which advertising is measured."

⁷On evaluation of the entire document:

The Commission finds that many of the challenged Anacin advertisements, when viewed in their entirety, did convey the message that the superiority of this product has been proven [footnote omitted]. It is immaterial that the word "established", which was used in the complaint, generally did not appear in the ads; the important consideration is the net impression conveyed to the public. *American Home Products*, 98 F.T.C. 136, 374 (1981), *aff'd*, 695 F.2d (3d Cir. 1982).

On the juxtaposition of phrases:

On this label, the statement "Kills Germs By Millions On Contact" immediately precedes the assertion "For General Oral Hygiene Bad Breath, Colds and Resultant Sore Throats" [footnote omitted]. By placing these two statements in close proximity, respondent has conveyed the message that since Listerine can kill millions of germs, it can *cure*, prevent and ameliorate colds and sore throats [footnote omitted]. *Warner Lambert*, 86 F.T.C. 1398, 1489-90 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978) (emphasis in original).

On the nature of the claim, *Firestone* is relevant. There the Commission noted that the alleged misrepresentation concerned the safety of respondent's product, "an issue of great significance to consumers. On this issue, the Commission has required scrupulous accuracy in advertising claims, for obvious reasons." 81 F.T.C. 398, 456 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).

In each of these cases, other factors, including in some instances surveys, were in evidence on the meaning of the ad.

⁸The evidence can consist of expert opinion, consumer testimony (particularly in cases involving oral representations), copy tests, surveys, or any other reliable evidence of consumer interpretation.

⁹As the Commission noted in the Cigarette rule, "The nature, appearance, or intended use of a product may create an impression on the mind of the consumer . . . and if the impression is false, and if the seller does not take adequate steps to correct it, he is responsible for an unlawful deception." Cigarette Rule Statement of Basis and Purpose, 29 FR 8324, 8352 (July 2, 1964).

¹⁰*Porter & Dietsch*, 90 F.T.C. 770, 873-74 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980); *Simeon Management Corp.*, 87 F.T.C. 1184, 1230 (1976), *aff'd*, 579 F.2d 1137 (9th Cir. 1978).

¹¹*See, e.g., Grolier*, 91 F.T.C. 315,480 (1978), *remanded on other grounds*, 615 F.2d 1215 (9th Cir. 1980), *modified on other grounds*, 98 F.T.C. 882 (1981), *reissued*, 99 F.T.C. 379 (1982).

¹²In *Peacock Buick*, 86 F.T.C. 1532 (1975), *aff'd*, 553 F.2d 97 (4th Cir. 1977), the Commission held that

absent a clear and early disclosure of the prior use of a late model car, deception can result from the setting in which a sale is made and the expectations of the buyer ... *Id.* at 1555.

[E]ven in the absence of affirmative misrepresentations, it is misleading for the seller of late model used cars to fail to reveal the particularized uses to which they have been put... When a later model used car is sold at close to list price ... the assumption likely to be made by some purchasers is that, absent disclosure to the contrary, such car has not previously been used in a way that might substantially impair its value. In such circumstances, failure to disclose a disfavored prior use may tend to mislead. *Id.* at 1557-58.

¹³In *Leonard Porter*, the Commission dismissed a complaint alleging that respondents' sale of unmarked products in Alaska led consumers to believe erroneously that they were handmade in Alaska by natives. Complaint counsel had failed to show that consumers of Alaskan craft assumed respondents' products were handmade by Alaskans in Alaska. The Commission was unwilling, absent evidence, to infer from a viewing of the items that the products would tend to mislead consumers.

By requiring such evidence, we do not imply that elaborate proof of consumer beliefs or behavior is necessary, even in a case such as this, to establish the requisite capacity to deceive. However, where visual inspection is inadequate, some extrinsic testimony evidence must be added. 88 F.T.C. 546, 626, n.5 (1976).

¹⁴*Bait and Switch Policy Protocol*, December 10, 1975; Guides Against Bait Advertising, 16 C.F.R. 238.0 (1967). 32 FR 15,540.

¹⁵*Encyclopedia Britannica* 87 F.T.C. 421, 497 (1976), *aff'd*, 605 F.2d 964 (7th Cir. 1979), *cert. denied*, 445 U.S. 934 (1980), *modified*, 100 F.T.C. 500 (1982).

¹⁶See the complaints in *BayleySuit*, C-3117 (consent agreement) (September 30, 1983) [102 F.T.C. 1285]; *Figgie International, Inc.*, D. 9166 (May 17, 1983).

¹⁷The Commission's complaints in *Chrysler Corporation*, 99 F.T.C. 347 (1982), and *Volkswagen of America*, 99 F.T.C. 446 (1982), alleged the failure to disclose accurate use and care instructions for replacing oil filters was deceptive. The complaint in *Ford Motor Co.*, D. 9154, 96 F.T.C. 362 (1980), charged Ford with failing to disclose a "piston scuffing" defect to purchasers and owners which was allegedly widespread and costly to repair. See also *General Motors*, D. 9145 (provisionally accepted consent agreement, April 26, 1983). [102 F.T.C. 1741]

¹⁸See *Jay Norris Corp.*, 91 F.T.C. 751 (1978), *aff'd with modified language in order*, 598 F.2d 1244 (2d Cir. 1979), *cert. denied*, 444 U.S. 980 (1979) (failure to consistently meet guarantee claims of "immediate and prompt" delivery as well as money back guarantees); *Southern States Distributing Co.*, 83 F.T.C. 1126 (1973) (failure to honor oral and written product maintenance guarantees, as represented); *Skylark Originals, Inc.*, 80 F.T.C. 337 (1972), *aff'd*, 475 F.2d 1396 (3d Cir. 1973) (failure to promptly honor moneyback guarantee as represented in advertisements and catalogs); *Capitol Manufacturing Corp.*, 73 F.T.C. 872 (1968) (failure to fully, satisfactorily and promptly meet all obligations and requirements under terms of service guarantee certificate).

¹⁹The evidence necessary to determine how reasonable consumers understand a representation is discussed in Section II of this letter.

²⁰An interpretation may be reasonable even though it is not shared by a majority of consumers in the relevant class, or by particularly sophisticated consumers. A material practice that misleads a significant minority of reasonable consumers is deceptive. *See Heinz W. Kirchner*, 63 F.T.C. 1282 (1963).

²¹A secondary message understood by reasonable consumers is actionable if deceptive even though the primary message is accurate. *Sears, Roebuck & Co.*, 95 F.T.C. 406, 511 (1980), *aff'd* 676 F.2d 385 (9th Cir. 1982); *Chrysler*, 87 F.T.C. 749 (1976), *aff'd*, 561 F.2d 357 (D.C. Cir.), *reissued* 90 F.T.C. 606 (1977); *Rhodes Pharmacal Co.*, 208 F.2d 382, 387 (7th Cir. 1953), *aff'd*, 348 U.S. 940 (1955).

²²*National Comm'n on Egg Nutrition*, 88 F.T.C. 89, 185 (1976), *enforced in part*, 570 F.2d 157 (7th Cir. 1977); *Jay Norris Corp.*, 91 F.T.C. 751, 836 (1978), *aff'd*, 598 F.2d 1244 (2d Cir. 1979).

²³*National Dynamics*, 82 F.T.C. 488, 524, 548 (1973), *aff'd*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974), *reissued* 85 F.T.C. 391 (1976).

²⁴*Warner-Lambert*, 86 F.T.C. 1398, 1415 n.4 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

²⁵*Grolier*, 91 F.T.C. 315, 430 (1978), *remanded on other grounds*, 615 F.2d 1215 (9th Cir. 1980), *modified on other grounds*, 98 F.T.C. 882 (1981), *reissued*, 99 F.T.C. 379 (1982).

²⁶*American Home Products*, 98 F.T.C. 136 (1981), *aff'd* 695 F.2d 681 (3d Cir. 1982). "... consumers may be led to expect, quite reasonably..." (at 386); "... consumers may reasonably believe..." (*Id.* n.52); "... would reasonably have been understood by consumers..." (at 371); "[t]he record shows that consumers could reasonably have understood this language . . ." (at 372). *See also*, pp. 373, 374, 375. *Bristol-Myers*, D. 8917 (July 5, 1983), appeal docketed, No. 83-4167 (2nd Cir. Sept. 12, 1983). "...ads must be judged by the impression they make on reasonable members of the public . . ." (Slip Op. at 4); ". . . consumers could reasonably have understood . . ." (Slip Op. at 7); ". . . consumers could reasonably infer . . ." (Slip Op. at 11) [102 F.T.C. 21 (1983)]. *Sterling Drug, Inc.*, D. 8919 (July 5, 1983), appeal docketed, No. 83-7700 (9th Cir. Sept. 14, 1983). "... consumers could reasonably assume . . ." (Slip Op. at 9); ". . . consumers could reasonably interpret the ads . . ." (Slip Op. at 33). [102 F.T.C. 395 (1983)]

²⁷*Horizon Corp.*, 97 F.T.C. 464, 810 n.13 (1981).

²⁸*Simeon Management*, 87 F.T.C. 1184, 1230 (1976).

²⁹The listed categories are merely examples. Whether children, terminally ill patients, or any other subgroup of the population will be considered a special audience depends on the specific factual context of the claim or the practice.

The Supreme Court has affirmed this approach. "The determination whether an advertisement is misleading requires consideration of the legal sophistication of its audience." *Bates v. Arizona*, 433 U.S. 350, 383 n.37 (1977).

³⁰In one case, the Commission's complaint focused on seriously ill persons. The ALJ summarized:

According to the complaint, the frustrations and hopes of the seriously ill and their families were exploited, and the representation had the tendency and capacity to induce the seriously ill to forego conventional medical treatment worsening their condition and in some cases hastening death, or to cause them to spend large amounts of money and to undergo the inconvenience of traveling for a non-existent "operation." *Travel King*, 86 F.T.C. 715, 719 (1975).

In a case involving a weight loss product, the Commission observed:

It is obvious that dieting is the conventional method of losing weight. But it is equally obvious that many people who need or want to lose weight regard dieting as bitter medicine. To these corpulent consumers the promises of weight loss without dieting are the Siren's call, and advertising that heralds unrestrained consumption while muting the inevitable need for temperance, if not abstinence, simply does not pass muster. *Porter & Dietsch*, 90 F.T.C. 770, 864-865 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980).

Children have also been the specific target of ads or practices. In *Ideal Toy*, the Commission adopted the Hearing Examiner's conclusion that:

False, misleading and deceptive advertising claims beamed at children tend to exploit unfairly a consumer group unqualified by age or experience to anticipate or appreciate the possibility that representations may be exaggerated or untrue. *Ideal Toy*, 64 F.T.C. 297, 310 (1964).

See also, Avalon Industries Inc., 83 F.T.C. 1728, 1750 (1974).

³¹*FTC v. Sterling Drug*, 317 F.2d 669, 674 (2d Cir. 1963).

³²Numerous cases exemplify this point. For instance, in *Pfizer*, the Commission ruled that "the net impression of the advertisement, evaluated from the perspective of the audience to whom the advertisement is directed, is controlling." 81 F.T.C. 23, 58 (1972).

In a subsequent case, the Commission explained that "[i]n evaluating advertising representations, we are required to look at the complete advertisement and formulate our opinions on them on the basis of the net general impression conveyed by them and not on isolated excerpts." *Standard Oil of Calif*, 84 F.T.C. 1401, 1471 (1974), *aff'd as modified*, 577 F.2d 653 (9th Cir. 1978), *reissued*, 96 F.T.C. 380 (1980).

The Third Circuit stated succinctly the Commission's standard. "The tendency of the advertising to deceive must be judged by viewing it as a whole, without emphasizing isolated words or

phrases apart from their context." *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977).

³³In *Litton Industries*, the Commission held that fine print disclosures that the surveys included only "Litton authorized" agencies were inadequate to remedy the deceptive characterization of the survey population in the headline. 97 F.T.C. 1, 71, n.6 (1981), *aff'd as modified*, 676 F.2d 364 (9th Cir. 1982). Compare the Commission's note in the same case that the fine print disclosure "Litton and one other brand" was reasonable to quote the claim that independent service technicians had been surveyed. "[F]ine print was a reasonable medium for disclosing a qualification of only limited relevance." 97 F.T.C. 1, 70, n.5 (1981).

In another case, the Commission held that the body of the ad corrected the possibly misleading headline because in order to enter the contest, the consumer had to read the text, and the text would eliminate any false impression stemming from the headline. *D.L. Blair*, 82 F.T.C. 234, 255-256 (1973).

In one case respondent's expert witness testified that the headline (and accompanying picture) of an ad would be the focal point of the first glance. He also told the administrative law judge that a consumer would spend [t]ypically a few seconds at most" on the ads at issue. *Crown Central*, 84 F.T.C. 1493, 1543 nn. 14-15 (1974).

³⁴In *Giant Food*, the Commission agreed with the examiner that the fine-print disclaimer was inadequate to correct a deceptive impression. The Commission quoted from the examiner's finding that "very few if any of the persons who would read Giant's advertisements would take the trouble to, or did, read the fine print disclaimer." 61 F.T.C. 326, 348 (1962).

Cf. Beneficial Corp. v. FTC, 542 P.2d 611, 618 (3d Cir. 1976), where the court reversed the Commission's opinion that no qualifying language could eliminate the deception stemming from use of the slogan "Instant Tax Refund."

³⁵"Respondents argue that the contracts which consumers signed indicated that credit life insurance was not required for financing, and that this disclosure obviated the possibility of deception. We disagree. It is clear from consumer testimony that oral deception was employed in some instances to cause consumers to ignore the warning in their sales agreement. . . ." *Peacock Buick*, 86 F.T.C. 1532, 1558-59 (1974).

³⁶*Exposition Press*, 295 F.2d 869, 873 (2d Cir. 1961); *Gimbel Bros.*, 61 F.T.C. 1051, 1066 (1962); *Carter Products*, 186 F.2d 821, 824 (1951).

By the same token, money-back guarantees do not eliminate deception. In *Sears*, the Commission observed:

A money-back guarantee is no defense to a charge of deceptive advertising.... A money-back guarantee does not compensate the consumer for the often considerable time and expense incident to returning a major-ticket item and obtaining a replacement.

Sears, Roebuck and Co., 95 F.T.C. 406, 518 (1980), *aff'd*, 676 F.2d 385 (9th Cir. 1982). However, the existence of a guarantee, if honored, has a bearing on whether the Commission

should exercise its discretion to prosecute. *See* Deceptive and Unsubstantiated Claims Policy Protocol, 1975.

³⁷*See American Home Products*, 98 F.T.C. 136, 370 (1981), *aff'd*, 695 F.2d 681, 688 (3d Cir. Dec. 3, 1982), Whether a disclosure on the label cures deception in advertising depends on the circumstances:

... it is well settled that dishonest advertising is not cured or excused by honest labeling [footnote omitted]. Whether the ill-effects of deceptive nondisclosure can be cured by a disclosure requirement limited to labeling, or whether a further requirement of disclosure in advertising should be imposed, is essentially a question of remedy. As such it is a matter within the sound discretion of the Commission [footnote omitted]. The question of whether in a particular case to require disclosure in advertising cannot be answered by application of any hard-and-fast principle. The test is simple and pragmatic: Is it likely that, unless such disclosure is made, a substantial body of consumers will be misled to their detriment? *Statement of Basis and Purpose for the Cigarette Advertising and Labeling Trade Regulation Rule*, 1965, pp. 89-90. 29 FR 8325 (1964).

Misleading "door openers" have also been found deceptive (*Encyclopedia Britannica*, 87 F.T.C. 421 (1976), *aff'd*, 605 F.2d 964 (7th Cir. 1979), *cert. denied*, 445 U.S. 934 (1980), *as modified*, 100 F.T.C. 500 (1982)), as have offers to sell that are not bona fide offers (*Seekonk Freezer Meats, Inc.*, 82 F.T.C. 1025 (1973)). In each of these instances, the truth is made known prior to purchase.

³⁸In the Listerine case, the Commission held that *pro forma* statements of no absolute prevention followed by promises of fewer colds did not cure or correct the false message that Listerine will prevent colds. *Warner Lambert* 86 F.T.C. 1398, 1414 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978).

³⁹*Chicago Metropolitan Pontiac Dealers' Ass'n*, C. 3110 (June 9, 1983). [101 F.T.C. 854 (1983)]

⁴⁰An opinion is a representation that expresses only the belief of the maker, without certainty, as to the existence of a fact, or his judgement as to quality, value, authenticity, or other matters of judgement. American Law Institute, *Restatement on Torts*, Second ¶ 538 A.

⁴¹*Id.* ¶ 539. At common law, a consumer can generally rely on an expert opinion. *Id.*, ¶ 542(a). For this reason, representations of expert opinion will generally be regarded as representations of fact.

⁴²"[T]here is a category of advertising themes, in the nature of puffing or other hyperbole, which do not amount to the type of affirmative product claims for which either the Commission or the consumer would expect documentation." *Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972).

The term "Puffing" refers generally to an expression of opinion not made as a representation of fact. A seller has some latitude in puffing his goods, but he is not authorized to misrepresent them or to assign to them benefits they do not possess [cite omitted]. Statements made for the purpose of deceiving prospective purchasers cannot

properly be characterized as mere puffing. *Wilmington Chemical*, 69 F.T.C. 828, 865 (1966).

⁴³In *Avalon Industries*, the ALJ observed that the "'ordinary person with a common degree of familiarity with industrial civilization' would expect a reasonable relationship between the size of package and the size of quantity of the contents. He would have no reason to anticipate slack filling." 83 F.T.C. 1728, 1750 (1974) (I.D.).

⁴⁴"A misleading claim or omission in advertising will violate Section 5 or Section 12, however, only if the omitted information would be a material factor in the consumer's decision to purchase the product." *American Home Products Corp.*, 98 F.T.C. 136, 368 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982). A claim is material if it is likely to affect consumer behavior. "Is it likely to affect the average consumer in deciding whether to purchase the advertised product-is there a material deception, in other words?" Statement of Basis and Purpose, *Cigarette Advertising and Labeling Rule*, 1965, pp. 86-87. 29 FR 8325 (1964).

⁴⁵Material information may affect conduct other than the decision to purchase a product. The Commission's complaint in *Volkswagen of America*, 99 F.T.C. 446 (1982), for example, was based on provision of inaccurate instructions for oil filter installation. In its *Restatement on Torts, Second*, the American Law Institute defines a material misrepresentation or omission as one which the reasonable person would regard as important in deciding how to act, or one which the maker knows that the recipient, because of his or her own peculiarities, is likely to consider important. Section 538(2). The Restatement explains that a material fact does not necessarily have to affect the finances of a transaction. "There are many more-or-less sentimental considerations that the ordinary man regards as important." Comment on Clause 2(a)(d).

⁴⁶In evaluating materiality, the Commission takes consumer preferences as given. Thus, if consumers prefer one product to another, the Commission need not determine whether that preference is objectively justified. See *Algoma Lumber*, 291 U.S. 54, 78 (1933). Similarly, objective differences among products are not material if the difference is not likely to affect consumer choices.

⁴⁷The Commission will always consider relevant and competent evidence offered to rebut presumptions of materiality.

⁴⁸Because this presumption is absent for some implied claims, the Commission will take special caution to ensure materiality exists in such cases.

⁴⁹*Central Hudson Gas & Electric Co. v. PSC*, 447 U.S. 557, 567 (1980).

⁵⁰*Cf. Restatement on Contracts, Second* ¶ 162(l).

⁵¹In *American Home Products*, the evidence was that the company intended to differentiate its products from aspirin. The very fact that AHP sought to distinguish its products from aspirin strongly implies that knowledge of the true ingredients of those products would be material to purchasers." *American Home Products*, 98 F.T.C. 136, 368 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982).

⁵²In *Fedders*, the ads represented that only Fedders gave the assurance of cooling on extra hot, humid days. "Such a representation is the *raison d'être* for an air conditioning unit-it is an extremely material representation." 85 F.T.C. 38, 61 (1975) (I.D.), *petition dismissed*, 529 F.2d 1398 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976).

⁵³"We note at the outset that both alleged misrepresentations go to the issue of the safety of respondent's product, an issue of great significance to consumers." *Firestone*, 81 F.T.C. 398, 456 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).

⁵⁴The Commission found that information that a product was effective in only the small minority of cases where tiredness symptoms are due to an iron deficiency, and that it was of no benefit in all other cases, was material. *J.B. Williams Co.*, 68 F.T.C. 481, 546 (1965), *aff'd*, 381 F.2d 884 (6th Cir. 1967).

⁵⁵As the Commission noted in *MacMillan, Inc.*:

In marketing their courses, respondents failed to adequately disclose the number of lesson assignments to be submitted in a course. These were material facts necessary for the student to calculate his tuition obligation, which was based on the number of lesson assignments he submitted for grading. The nondisclosure of these material facts combined with the confusion arising from LaSalle's inconsistent use of terminology had the capacity to mislead students about the nature and extent of their tuition obligation. *MacMillan, Inc.*, 96 F.T.C. 208, 303-304 (1980).

See also, Peacock Buick, 86 F.T.C. 1532, 1562 (1975), *aff'd*, 553 F.2d 97 (4th Cir. 1977).

⁵⁶*Simeon Management Corp.*, 87 F.T.C. 1184 (1976), *aff'd*, 579 F.2d 1137, 1168, n.10 (9th Cir. 1978).

⁵⁷In *American Home Products*, the Commission approved the ALJ's finding of materiality from an economic perspective:

If the record contained evidence of a significant disparity between the prices of Anacin and plain aspirin, it would form a further basis for a finding of materiality. That is, there is a reason to believe consumers are willing to pay a premium for a product believed to contain a special analgesic ingredient but not for a product whose analgesic is ordinary aspirin. *American Home Products*, 98 F.T.C. 136, 369 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982).

⁵⁸The prohibitions of Section 5 are intended to prevent injury to competitors as well as to consumers. The Commission regards injury to competitors as identical to injury to consumers. Advertising and legitimate marketing techniques are intended to "lure" competitors by directing business to the advertiser. In fact, vigorous competitive advertising can actually benefit consumers by lowering prices, encouraging product innovation, and increasing the specificity and amount of information available to consumers. Deceptive practices injure both competitors and consumers because consumers who preferred the competitor's product are wrongly diverted.



Mars Petcare Settles False Advertising Charges Related to Its Eukanuba Dog Food

Company's Ads Claimed the Brand Could Increase Dogs' Lifespan by 30 Percent or More

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FOR RELEASE

August 4, 2016

TAGS: [Food and Beverages](#) | [Bureau of Consumer Protection](#) | [Western Region](#) | [Consumer Protection](#) | [Advertising and Marketing](#) | [Health Claims](#)

Mars Petcare U.S., Inc., has agreed to settle Federal Trade Commission charges that it falsely advertised the health benefits of its Eukanuba brand dog food. Specifically, the FTC alleges that the company claimed, but could not prove, that a 10-year study found that dogs fed Eukanuba could extend their expected lifespan by 30 percent or more.

"Two-thirds of all Americans have pets at home, and they spend billions of dollars to ensure that their pets are healthy and well-fed," said Jessica Rich, Director of the FTC's Bureau of Consumer Protection. "Pet owners count on ads to be truthful and not to misrepresent health-related benefits. In this case, Mars Petcare simply did not have the evidence to back up the life-extending claims it made about its Eukanuba dog food."

According to the FTC's complaint, in 2015, Mars Petcare ran ads for Eukanuba on television, in print, and on the Internet, claiming that the dog food could increase the longevity of dogs', based on a 10-year study of dogs that were fed Eukanuba and implying that the increase in lifespan was 30 percent or more.

One TV ad stated, for example:

"10 years ago, we launched a long life study. What we observed was astonishing. With Eukanuba and proper care, dogs in the study were able to live beyond their typical lifespan." The ad then showed a dog named "Iowa" who was 17 years old, while "the typical Labrador lifespan: [is] 12 years." The implication was that Iowa had lived 30 percent longer than expected for her breed because she was fed Eukanuba.

The FTC alleges that the longevity claims are false or unsubstantiated and that the claim that longevity was proven through scientific evidence is false.

The proposed order settling the FTC's charges prohibits Mars Petcare from engaging in similar deceptive acts or practices in the future. First, it prohibits the company from making any misleading or unsubstantiated claims that its

Eukanuba-brand pet food or any other pet food will enable any dogs to extend their lifespan by 30 percent or more or live exceptionally long lives. It also prohibits the company from making misleading or unsubstantiated claims regarding the health benefits of any pet food, and requires the company to have competent and reliable scientific evidence to back up any such claims.

Finally, the proposed order prohibits Mars Petcare, when advertising any pet food, from misrepresenting the existence, results, conclusions, or interpretations of any study, or falsely stating that the health benefits claimed are scientifically proven. It also contains compliance and monitoring requirements to ensure the company abides by its terms.

The Commission vote to issue the administrative complaint and to accept the proposed consent agreement was 3-0. The FTC will publish a description of the consent agreement package in the Federal Register shortly.

The agreement will be subject to public comment for 30 days, beginning today and continuing through September 6, 2016, after which the Commission will decide whether to make the proposed consent order final. Interested parties can [submit comments electronically](#) by following the instructions in the "Invitation to Comment" part of the "Supplementary Information" section of the Federal Register notice.

NOTE: The Commission issues an administrative complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of \$40,000.

The Federal Trade Commission works to promote competition, and [protect and educate consumers](#). You can [learn more about consumer topics](#) and file a [consumer complaint online](#) or by calling 1-877-FTC-HELP (382-4357). Like the FTC on [Facebook](#), follow us on [Twitter](#), read our [blogs](#) and [subscribe to press releases](#) for the latest FTC news and resources.

PRESS RELEASE REFERENCE:

[FTC Approves Final Order Settling Charges that Mars Petcare Made False Health Claims for Its Eukanuba Brand Dog Food](#)

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FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Approves Final Consent Orders Settling Charges that Companies Deceptively Claimed Their Genetically Modified Nutritional Supplements Could Treat Diseases

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FOR YOUR INFORMATION

May 12, 2014

TAGS: [deceptive/misleading conduct](#) | [restrictions on advertising](#) | [retailing](#) | [Health Care](#) | [Over-the-Counter Drugs and Devices](#) | [Bureau of Consumer Protection](#) | [Consumer Protection](#) | [Advertising and Marketing](#) | [Health Claims](#) | [Data Security](#)

Following a public comment period, the Federal Trade Commission has approved final consent orders settling charges that two marketers of genetically customized nutritional supplements deceptively advertised that their personalized nutritional supplements treat diabetes, heart disease, arthritis, insomnia, and other ailments. The orders also settle charges that the companies' data security practices were lax. The Commission also approved responses to the two comments received during the public comment period.

First announced in January 2014, this case marks the first law enforcement action taken by the Commission against marketers of purported personalized genomics products. The final settlements prohibit GeneLink, Inc. and its former subsidiary, foruTM International Corp., from claiming that any drug, food, or cosmetic will treat, prevent, mitigate, or reduce the risk of any disease – by modulating the effect of genes, or based on a consumer's customized genetic assessment – unless the claim is true and supported by at least two adequate and well-controlled studies. Under the orders, claims that a product effectively treats or prevents a disease in persons with a particular genetic variation must be backed up with randomized controlled trials conducted on subjects who have that genetic variation. The orders also prohibit GeneLink and foruTM International from misrepresenting scientific research regarding any drug, food, or cosmetic, or any genetic test or assessment and from providing their affiliates with the means to make the prohibited health claims.

Under the orders, the companies also are prohibited from misrepresenting their privacy and security practices. They are required to establish and maintain comprehensive data security programs and submit to security audits by independent auditors every other year for 20 years.

The Commission vote to approve the final orders in this case was 3-1-1, with Commissioner Ohlhausen dissenting and Commissioner McSweeney not participating. (FTC File No. 112 3095; the staff contact is Carolyn Hann, Bureau of Consumer Protection, 202-326-2745.)

The Federal Trade Commission works for consumers to prevent fraudulent, deceptive, and unfair business practices and to provide information to help spot, stop, and avoid them. To file a complaint in English or Spanish, visit the FTC's online [Complaint Assistant](#) or call 1-877-FTC-HELP (1-877-382-4357). The FTC enters complaints into Consumer Sentinel, a secure, online database available to more than 2,000 civil and criminal law enforcement agencies in the U.S. and abroad. The FTC's website provides [free information on a variety of consumer topics](#). Like the FTC on [Facebook](#), follow us on [Twitter](#), and [subscribe to press releases](#) for the latest FTC news and resources.

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ftc.gov

Exhibit 5

MATT SIMON SCIENCE 09.20.17 11:00 AM

THE IMPOSSIBLE BURGER: INSIDE THE STRANGE SCIENCE OF THE FAKE MEAT THAT 'BLEEDS'

THE COOK, COMPLETE with hair net, lays the red patty down on the grill and gives it a press with a spatula. And there, that unmistakable sizzle and smell. She flips the patty and gives it another press, lets it sit, presses it, and pulls it off the grill and onto a bun.

This is no diner, and this is no ordinary cook. She's wearing not an apron, but a lab coat and safety goggles, standing in a lab-kitchen hybrid in a Silicon Valley office park. Here a company called Impossible Foods has over the last six years done something not quite impossible, but definitely unlikely: Engineering a plant-based burger that smells, tastes, looks, and even feels like ground beef.

There are other veggie burgers on the market, of course, but Impossible Foods wants to sell consumers a real meat analog—one that requires a very different kind of engineering than your Boca or black bean burgers. So WIRED wants to take you

on the deepest dive yet into the science behind the Impossible Burger.

Biting into an Impossible Burger is to bite into a future in which humanity has to somehow feed an exploding population and not further imperil the planet with ever more livestock. Because livestock, and cows in particular, go through unfathomable amounts of food and water (up to 11,000 gallons a year per cow) and take up vast stretches of land. And their gastrointestinal methane emissions aren't doing the fight against global warming any favors either (cattle gas makes up 10 percent of greenhouse gas emissions worldwide).

This is the inside story of the engineering of the Impossible Burger, the fake meat on a mission to change the world with one part soy plant, one part genetically engineered yeast—and one part activism. As it happens, though, you can't raise hell in the food supply without first raising a few eyebrows.

The Lean, Mean Heme Machine

What makes a burger a burger? The smell, for one, and taste and texture, all working in concert to create something animal. It's loaded with all manner of proteins that interact with each other in unique ways, creating a puzzle of sorts. But Impossible Foods thinks the essence of a meat lies in a compound called heme, which gives ground beef its color and vaguely metallic taste—thanks to iron in the heme molecule. In blood, heme lives in a protein called hemoglobin; in muscle, it's in myoglobin.

Interestingly, you'll find globins (a class of proteins) not just across the animal kingdom, but in plants as well. Soy roots, for example, carry a version called leghemoglobin, which also carries heme. Leghemoglobin in soy and myoglobin in meat

share a similar 3-D structure consisting of what's known as an alpha helical globin fold, which wraps around the heme.

So what if you could extract the heme from a plant to obtain that secret ingredient in ground beef? Well, the main problem, Impossible Foods found, is that you'd need a heck of a lot of soy: One acre of soybeans would yield just a kilogram of soy leghemoglobin.

MORE FOOD SCIENCE

JOE RAY

Wheat Nerds and Scientists Join Forces to Build a Better Bread

ADAM ROGERS

Who Wants Disease-Resistant GM Tomatoes? Probably Not Europe

SARAH ZHANG

Farmers Are Manipulating Microbiomes to Help Crops Grow

Impossible Foods founder and CEO Pat Brown figured out how to hack together a better way. Technicians take genes that code for the soy leghemoglobin protein and insert them into a species of yeast called *Pichia pastoris*. They then feed the modified yeast sugar and minerals, prompting it to grow and replicate and manufacture heme with a fraction of the footprint of field-grown soy. With this process, Impossible Foods claims it produces a fake burger that uses a 20th of the land required for feeding and raising livestock and uses a quarter of the water, while producing an eighth of the greenhouse gases (based on a metric called a *life cycle assessment*).

Now, engineering a “beef” burger from scratch is of course about more than just heme, which Impossible Foods bills as its essential ingredient. Ground beef features a galaxy of different compounds that interact with each other, transforming as the meat cooks. To piece together a plant-based burger that’s indistinguishable from the real thing, you need to identify and recreate as many of those flavors as possible.

To do this, Impossible Foods is using what's known as a gas chromatography mass spectrometry system. This heats a sample of beef, releasing aromas that bind to a piece of fiber. The machine then isolates and identifies the individual compounds responsible for those aromas. “So we will now have kind of a fingerprint of every single aroma that is in beef,” says Celeste Holz-Schietinger, principal scientist at Impossible Foods. “Then we can say, How close is the Impossible Burger? Where can we make improvements and iterate to identify how to make each of those particular flavor compounds?”

This sort of deconstruction is common in food science, a way to understand exactly how different compounds produce different flavors and aromas. “In theory, if you knew everything that was there in the right proportions, you could recreate from the chemicals themselves that specific flavor or fragrance,” says Staci Simonich, a chemist at Oregon State University.



WIRED

Then there's the problem of texture. Nothing feels quite like ground beef. So Impossible Foods isolates individual proteins in the meat. "Then as we identify what those particular protein properties are, we go and look at plants for plant proteins that have those same properties," says Holz-Schietinger. Plant proteins tend to taste more bitter, so Impossible Foods has to develop proteins with a cleaner taste.

What they've landed on in the current iteration is a surprising mix. Ingredients include wheat protein, to give the burger that firmness and chew. And potato protein, which allows the burger to hold water and transition from a softer state to a more solid state during cooking. For fat, Impossible Foods uses coconut with the flavor sucked out. And then of course you need the leghemoglobin for heme, which drives home the flavor of "meat."

For something that so accurately mimics the taste and look and feel and smell of meat (and trust us, it does), the Impossible Burger is actually not all that complex. "Earlier iterations were much more complex because we didn't fully understand it," says Holz-Schietinger (experiments with cucumber and the famously smelly durian fruit didn't pan

out, nor did trying to replicate the different connective tissues of a cow). “Now we understand which each component drives each sensory experience.”

At the moment, the Impossible Burger is only available in select restaurants, though Impossible Foods just opened a plant with the idea of increasing production from 300,000 pounds a month to a million. But as they focus on expansion, some critics are raising questions about the burger of tomorrow.

Government, Meet the Future. The Future, Government

In 2014, Impossible Foods filed what's known as a GRAS notice, or “generally recognized as safe,” with the FDA. In it, the company listed the reasons it considered soy leghemoglobin safe for humans to consume. Leghemoglobin, they argued, is chemically similar to other globins considered safe, so it should carry the same confidence with consumers. Food companies aren't required to tell the FDA when they're introducing new ingredients, and filing this sort of self GRAS determination is not mandatory, but Impossible Foods says it did so in the name of transparency.

“Leghemoglobin is structurally similar to proteins that we consume all the time,” says Impossible Foods' chief science officer David Lipman. “But we did the toxicity studies anyway and they showed that that was safe.” They compared the protein to known allergens, for instance, and found no matches. The company also got the OK from a panel of experts, including food scientist Michael Pariza at the University of Wisconsin, Madison.

But the company didn't get the blessing it was looking for from the FDA. As detailed in documents FOIA'ed by environmental groups and published by The New York Times in August, the FDA questioned the company's conclusions. "FDA believes that the arguments presented, individually and collectively, do not establish the safety of SLH [soy leghemoglobin] for consumption, nor do they point to a general recognition of safety..." the FDA wrote in a memo. That is not to say the FDA concluded leghemoglobin to be unsafe, just that it had questions.

The FDA also noted that the company's engineered yeast doesn't just produce leghemoglobin—it also produces 40 other normally occurring yeast proteins that end up in the burger, which "raises further question on how the safety argument could be made based solely on SLH." Impossible Foods insists these proteins are safe, and notes that the yeast it has engineered is non-toxic, and that its toxicity studies examined the whole leghemoglobin ingredient.

Impossible Foods withdrew its GRAS notice in November 2015 to perform a new study. They fed rats more than 200 times the amount of the leghemoglobin ingredient than the average American would consume if the ground beef in their diet—an average of 25 grams a day—was replaced with

Impossible's fake meat (adjusted for weight). They found no adverse effects.

Meanwhile, the Impossible Burger is on the market, which has some environmental groups peeved. That and there's the larger question of whether GRAS notifications should be voluntary or mandatory. "The generally recognized as safe exception was meant for common food ingredients, not for the leading-edge products, especially the innovative like the leghemoglobin," says Tom Neltner, chemicals policy director at the Environmental Defense Fund, which was not involved in the FOIA. "We don't think it should be a voluntary review, we don't think the law allows it." Accordingly, the group is suing the FDA over the agency's GRAS process.



WIRED

Others are concerned that leghemoglobin—again, a new ingredient in the food supply, since humans don't typically eat soy roots—hasn't gone through enough testing to prove it's safe, and agree with the FDA that Impossible Foods' GRAS notification came up short. "The point of some of us that are being critical of this is not that everything that's engineered is unsafe or anything like that," says Michael Hansen, senior staff scientist at the Consumers Union, which was also not

involved in the FOIA. "It's like, look, any new food ingredient, some new food additive, of course it should go through a safety assessment process."

Hansen takes issue with the idea that leghemoglobin is similar to other edible globins are therefore safe. "As the FDA pointed out in their response, just because proteins have similar functions or similar three-dimensional structures, doesn't mean that they're similar," Hansen says. "They can have a very different amino acid sequence, and just slight changes can have impacts."

This is what happens when the future of food lands on the government's plate. The central question: Should Americans trust companies to do their own food safety testing, or should that always be the job of the feds?

The reality is, different kinds of modified foods attract different levels of regulatory attention. "It is a patchwork system with little rhyme or reason," says crop scientist [Wayne Parrott](#) of the University of Georgia. "It depends on what is done, how it is done, and its intended use." You hear plenty about the crops, and most certainly about the [long hullabaloo over that GM salmon](#). But not engineered microorganisms, which are extremely common. Why?

"Out of sight, out of mind," says Parrott. "And people also get more emotional over animals than they do over other things. With the salmon it was political. Very, very political."

Really, there's no inherent danger in genetically modifying a food. After all, the FDA wasn't raising its voice about soy leghemoglobin because it comes from genetically engineered yeast. The agency's job is to determine the safety of foods. "Any risk that's associated comes from traits," Parrott says. "It doesn't come from the way you put those traits in there."

This is only the beginning of a new era of high-tech, genetically engineered foods. Because if we want to feed a rapidly expanding species on a planet that stays the same size, we're going to need to hack the food supply. Our crops will have to weather a climate in chaos. "We want to improve efficiency so we can feed 9 billion people without more land, without more water, without more fertilizer or pesticides," says Parrott.

And humanity will sure as hell have to cut back on its meat consumption. "We'll change the world more dramatically than any company possibly in history has ever done it," says Impossible Foods founder Brown. "Because when you look at the impact of the system we're replacing, almost half of the land area of Earth is being occupied by the animal farming industry, grazing, or feed crop production." That system, of course, will not give up ground quietly.

But who knows. Maybe shocking the system isn't so impossible after all.

TGI Fridays to Run Meatless Monday Campaign After Vegan Burger Launch

JANUARY 9, 2018 by **JILL ETTINGER**

1288

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iStock/BreatheFitness

With the recent addition of Beyond Meat's vegan Beyond Burger to more than 450 U.S. locations, **TGI Fridays** announced yesterday that it's also joining the ever-popular **Meatless Monday** campaign, which encourages people to go meatless on Mondays for their health and for the planet.

"Appealing to a more food-forward consumer is a key priority for Fridays in 2018," David Spirito, executive culinary director for the chain, said in a statement. "In answering guests' demand for nutritional menu items that fit their lifestyle needs, we saw an opportunity to introduce newly expanded options like plant-based protein. With **Beyond Burger**,

diners will have a sensory experience of a traditional burger without sacrificing taste.”

TGI Fridays won’t be pulling meat off of its menus on Mondays, but it will be collaborating with the Meatless Monday campaign in exclusive online promotional activities through major social media networks in a plan the chain says “has the potential of drawing diverse consumers to the meat-centric chain [for meatless meals].”

Meatless Monday has seen an uptick in popularity in recent years, and according to a 2017 survey, nearly one-third of consumers would support seeing Meatless Monday campaigns promoted at fast-food or quick-service restaurants.

“We’re excited that TGI Fridays, an iconic global restaurant brand, is leveraging Monday as a day to attract consumers to try Beyond Burger and Fridays’ other plant-based selections, without taking meat off their menu,” Dana Smith, Meatless Monday campaign director, said. “Our research shows that choosing meatless options, even one day a week, can help make a difference in our personal health and the health of our planet.”

The Beyond Burger is the plant-based burger that looks, cooks, and tastes like a traditional burger. But the patty is made entirely from plants — peas, beets, and coconut oil. It’s become the flagship product for Southern California’s Beyond Meat, which strategically merchandises its products adjacent to supermarket meat counters. The company recently announced the launch of Beyond Sausage, which is currently only available at the Boulder, Colo., Whole Foods Market.

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Protein & fat claim based on 10g of protein & 11g of fat in 55g of raw 80% lean ground beef.

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Calories 80

Calories from fat 30

Bill Gates and Richard Branson Back Startup That Grows 'Clean Meat'

By **Shruti Singh**

August 23, 2017, 12:01 PM EDT

Updated on August 24, 2017, 12:00 AM EDT

- Memphis Meats produces beef, chicken from animal cells
- Branson sees all meat 'clean' or plant-based in 30 years

Cargill Inc., one of the largest global agricultural companies, has joined [Bill Gates](https://www.bloomberg.com/billionaires/id/1390479) and other business giants to invest in a nascent technology to make meat from self-producing animal cells amid rising consumer demand for protein that's less reliant on feed, land and water.

Memphis Meats, which produces beef, chicken and duck directly from animal cells without raising and slaughtering livestock or poultry, raised \$17 million from investors including Cargill, Gates and billionaire [Richard Branson](https://www.bloomberg.com/billionaires/id/14006795), according to a [statement](https://static1.squarespace.com/static/5674c0c22399a3a13cbc3af2/t/599d77dfa803bbe20ff02424/1503492063640/Memphis+Meats+-+Press+Release+23+Aug+2017+vFF.pdf) [Tuesday](https://static1.squarespace.com/static/5674c0c22399a3a13cbc3af2/t/599d77dfa803bbe20ff02424/1503492063640/Memphis+Meats+-+Press+Release+23+Aug+2017+vFF.pdf) on the San Francisco-based startup's website. The fundraising round was led by venture-capital firm DFJ, which has previously backed several social-minded retail [startups](https://www.bloomberg.com/news/features/2017-05-18/the-barbarians-are-at-etsy-s-hand-hewn-responsibly-sourced-gates).

"I'm thrilled to have invested in Memphis Meats," Branson said in an email in response to questions from Bloomberg News. "I believe that in 30 years or so we will no longer need to kill any animals and that all meat will either be clean or plant-based, taste the same and also be much healthier for everyone."

This is the latest move by an agricultural giant to respond to consumers, especially Millennials, who are rapidly leaving their mark on the U.S. food world. That's happening through surging demand for organic products, increasing focus on food that's considered sustainable and greater attention on animal treatment. Big poultry and livestock processors have started to take up alternatives to traditional meat.


"The world loves to eat meat, and it is core to many of our cultures and traditions," Uma Valeti, co-founder and chief executive officer of Memphis Meats, said in the statement. "The way conventional meat is produced today creates challenges for the environment, animal welfare and human health. These are problems that everyone wants to solve."

'Clean Meat'

To date, Memphis Meats has raised \$22 million, signaling a commitment to the "clean-meat movement," the company said.

Cargill has "taken an equity position in Memphis Meats' first series of funding," Sonya Roberts, the president of growth ventures at Cargill Protein, said in an email, without disclosing the investment amount.

"Our equity position with Memphis Meats gives Cargill entry into the cultured protein market and allows us to work together to further innovate and commercialize," Roberts said. "We believe that consumers will continue to crave meat, and we aim to bring it to the table, as sustainably and cost-effectively as we can. Cultured meats and conventionally produced meats will both play a role in meeting that demand."

The investment is just the most recent by traditional meat companies. Tyson Foods Inc., the largest U.S. meat producer, has created a venture capital fund focused on investing in companies “to sustainably feed” the world’s growing population and in December announced a stake in plant-based protein producer [Beyond Meat](#) , which counts Gates among its early funders.

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03.29.17

In Its New Factory, Impossible Foods Will Make 12 Million Pounds Of Plant-Based Burgers A Year

The exciting new plant-based burger that bleeds like real meat is scaling up to reach more customers: It wants to be in 1,000 restaurants by the end of the year.



Photo: courtesy Impossible Foods PHOTO: COURTESY IMPOSSIBLE FOODS

BY ADELE PETERS

3 MINUTE READ

Inside a former baked-goods factory near the Oakland airport, a construction crew is installing giant vats that will soon be used to scale up production of the Impossible Burger—a plant-based meat designed to look and taste good enough that meat eaters will want to order it, not vegetarians.

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The “meat,” developed by a team led by former Stanford biochemistry professor Patrick Brown, is currently being produced in a 10,000-square-foot pilot facility in Silicon Valley and a 1,500-square foot space in New Jersey. The new facility, at around 60,000 square feet, will dramatically scale up production capacity. When the factory is fully ramped up, it will be able to produce at least 1 million pounds of Impossible Burger meat a month, or 250 times more than today.

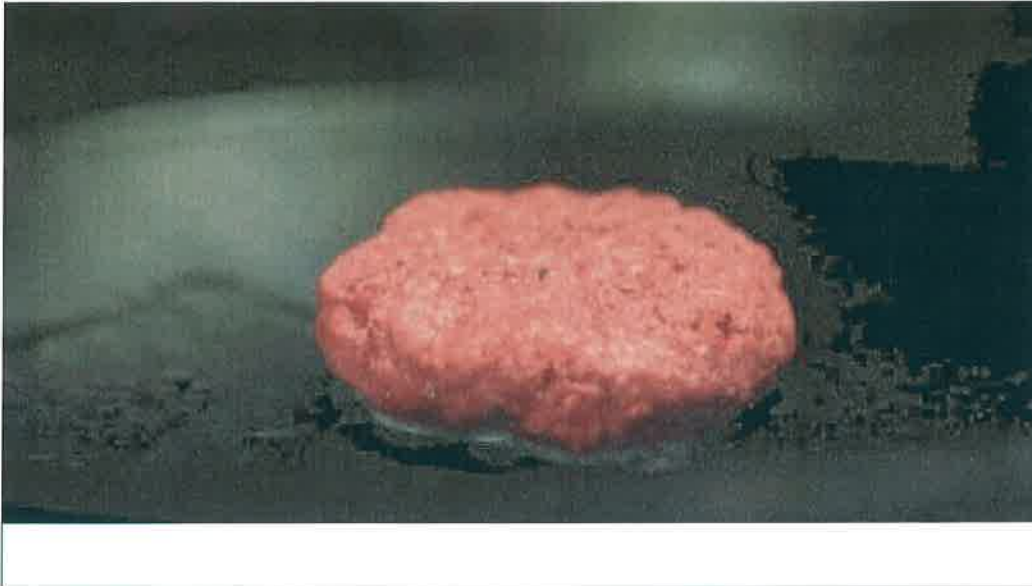


PHOTO: COURTESY IMPOSSIBLE FOODS

“It will enable us to go from something that is scarce—and we’re constantly getting complaints from customers about the fact that they can’t buy them at their local restaurant—and start to make it ubiquitous,” Brown said at an event launching the new factory.

The burger is currently available at 11 restaurants, including 3 that launched it on March 23. But by the end of the year, the company expects to supply 1,000 restaurants. It just signed a deal to have the burgers featured in the [San Francisco Giant’s baseball stadium](#).



PHOTO: COURTESY IMPOSSIBLE FOODS

For the company, achieving scale is a critical part of achieving its mission. Brown started working on the project while thinking about the problem of climate change; raising cows and other animals for meat is one of the world’s largest sources of greenhouse gases. It also uses

and pollutes more water than any other industry, and drives deforestation. But he realized that the majority of the world wouldn't voluntarily go vegetarian for those reasons.

"Billions of people around the world who love meat are not going to stop demanding it, so we just have to find a better way to produce it," he says.



PHOTO: COURTESY IMPOSSIBLE FOODS

The team studied the properties of meat—particularly heme, the molecule that makes blood red and gives meat a meaty taste—and then experimented with recreating those properties using only ingredients from plants.

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“When you think about meat, there’s the muscle, there’s the connective tissue, there’s the fat, so we had to figure out how to mimic those parts of beef to figure out how to experience the texture, but also the taste,” Don DeMasi, senior vice president of engineering for Impossible Foods, tells *Fast Company*.

The result looks like it was made from a cow, not plants. The handful of chefs who were given first access to the product say they think of it as meat. “It kind of made this transition in my mind to be—it’s just another kind of meat,” says chef Traci Des Jardins, who has been serving Impossible burgers at her San Francisco restaurant Jardinière for about a year, and now is also serving it at Public House, her restaurant at the city’s ballpark.



PHOTO: COURTESY IMPOSSIBLE FOODS

Before it’s cooked, the product is red like raw beef; as it cooks, it browns. As the heme mixes with juices and oozes out, it can look like it’s bleeding. “You’re seeing the exact same cooking chemistry that you see in meat, literally,” says Brown.

As the company scales up its beef alternative, it will focus on restaurants. In a year, it says, U.S. restaurants serve more than 5 billion pounds of burgers, and Impossible wants its 12 million pounds to be among them. Retail will come later, along with other products that are currently in development, such as poultry and steak.

“Our long-term goal is to basically develop a new and better way to create all the foods we make from animals,” says Brown.



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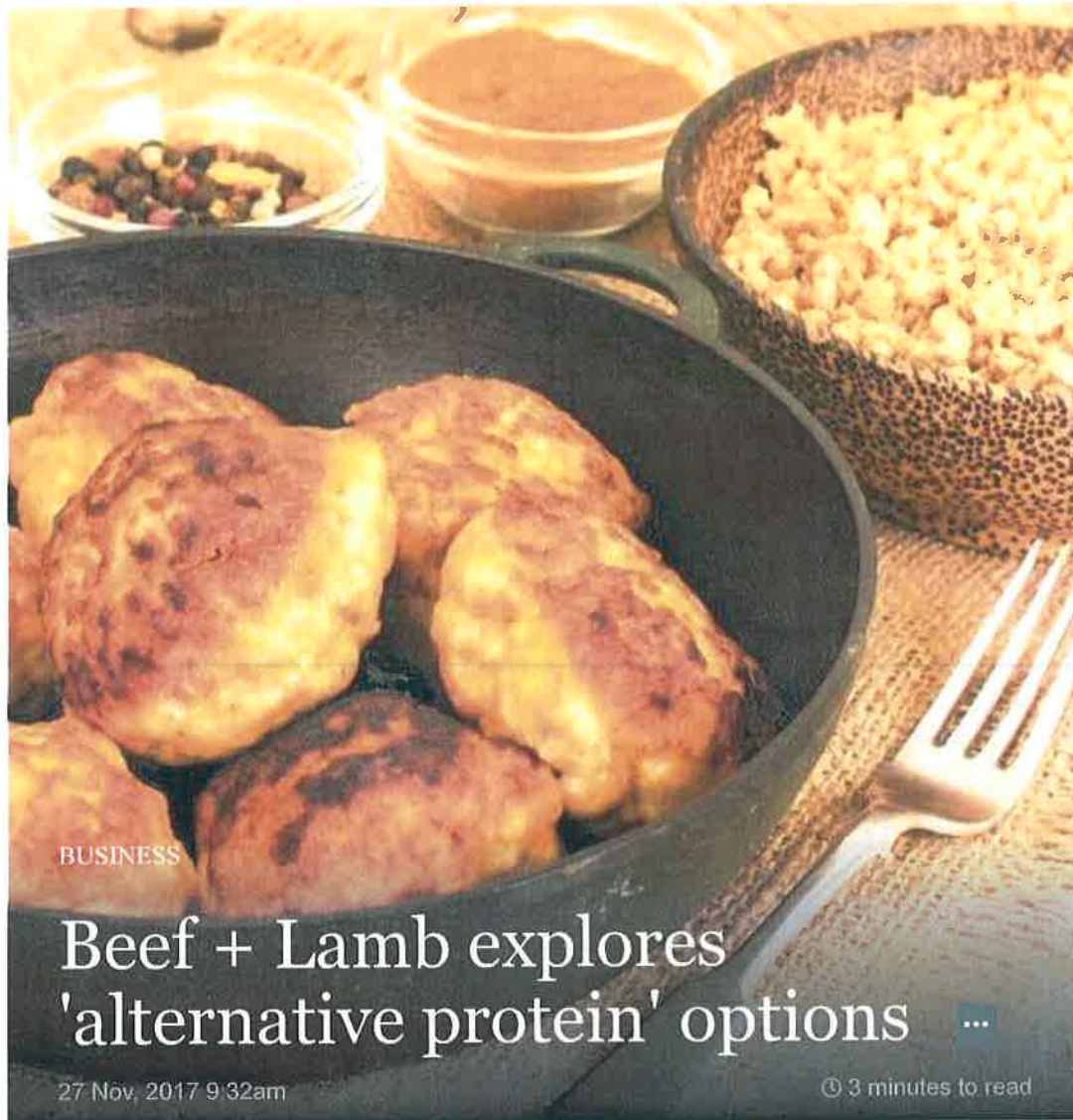
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Beef + Lamb explores 'alternative protein' options ...

27 Nov, 2017 9:32am

🕒 3 minutes to read

Beef + Lamb launched a project in August to understand the production technologies, business models and products of plant-based, lab-grown and insect proteins. Photo / 123RF

BusinessDesk
By: Rebecca Howard



Beef + Lamb New Zealand is carrying out consumer research into alternative proteins in China and San Francisco in response to the rise of the rival products and wants to report back to the sector before the end of the year.

"What we have discovered is that for better or worse alternative protein is here. We are not seeing it as a

Case 2:18-cv-04173-FJC Document 45-1 Filed 01/18/19 Page 107 of 124

alternative for certain types of consumers. The consumer research that we doing is to understand who those consumers are and what's driving that behaviour," Damien Cullinan, market innovation manager for Beef + Lamb, told BusinessDesk.

The industry lobby group launched a project in August to understand the production technologies, business models and products, and how consumers are responding along with the threats and opportunities posed by plant-based, lab-grown and insect proteins.

It is trying to separate the "hype from the reality" and "we are going hammer and tongs" to present an internal report within the next four weeks to determine future strategy, said Cullinan. Beef + Lamb will then look at what it presents publically as it doesn't want to provide competitors with "a potential playbook or a look at our strategy," he said.

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Cullinan noted that while it's not clear what the eventual impact will be, the technology is moving extremely fast. So-called synthetic or alternative proteins have gone from the world's first lab-grown hamburger unveiled in 2013 to now being available on the menu in some US restaurants.

While Beef + Lamb sees it as an alternative rather than a replacement, others are direr. The Prime Minister's chief science adviser Peter Gluckman has said there is a growing consumer appetite around the world for synthetic alternatives to meat and milk, which poses an "existential threat" to the country's economic fortunes. Earlier this week, Rabobank said alternative proteins are on the verge of becoming mainstream and "stealing" growth from traditional meat products.



Earlier this week, Rabobank said alternative proteins, such as insects (pictured) are on the verge of becoming mainstream and "stealing" growth from traditional meat products. Photo / 123RF



Cullinan said Beef + Lamb is not downplaying the opportunities or challenges to the industry: "We are not burying our heads in the sand and saying there is nothing we can do about it," he said.

"This is definitely something we have been taking seriously for a while and we have a very robust process ... we are quite

excited about what we are seeing. There is an opportunity for the industry," he said.

Among other things, he noted plant-based synthetic foods rely on genetically modified ingredients to enhance the taste and texture and that is something New Zealand - and consumers around the world - need to be aware of.

"People are making a bit of a trade-off. If they have decided for whatever reason they don't want product A, product B is not product A but it has got some other stuff they may be unaware of," he said.

Against that backdrop, New Zealand's natural and grass-fed based farming system remains competitive.

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China signs \$300m deal to buy lab-grown meat from Israel in move welcomed by vegans

For many environmental and animal rights groups, lab meat is seen as a positive move away from the slaughter of billions of animals

Rachel Roberts | Saturday 16 September 2017 17:32 BST | [38](#) comments



China has signed a £300 million deal to purchase 'meat' grown in a laboratory in Israel in a drive towards less meat consumption in the country. The panda bear, native to China, is a vegetarian. *Issei Kato/Reuters*

China has signed a \$300m deal to [purchase](#) meat grown in a laboratory in [Israel](#) in a deal that could open a lucrative floodgate for [vegan](#) food manufacturers into the world's most populous country.

Lab meat - also known as cultured or bio meat - is grown in a laboratory using animal cells, making some vegans opposed to the concept - but several environmental and animal rights groups have welcomed it as an exciting development.

Bruce Friedrich, head of the Good Food Institute (GFI), an organisation which promotes meat alternatives, hailed the deal as a "colossal market opportunity".

He believes the deal "could put [clean] meat onto the radar of Chinese officials who have the capacity to steer billions of dollars into this technology".



Although the use of animal cells means it is not entirely slaughter-free, [scientists](#) are currently working on developing a totally synthetic substitute.

For many environmental and animal rights groups, lab meat is seen as a positive move away from the slaughter of billions of [animals](#), as well as being a greener option than traditional factory farming.

China is not generally regarded as a world leader in environmental issues, so its deal with three Israeli companies - SuperMeat, Future Meat Technologies, and Meat the Future - has been welcomed by some groups as a sign that China is committed to reducing its greenhouse gas emissions.



We need to end the meat and dairy industry altogether

China currently imports around £10bn worth of meat annually to help feed its population of more than 1.4 billion people.

China's communist government has outlined a plan to reduce its citizens' meat consumption by 50 per cent, in a move welcomed by climate campaigners as a way to mitigate global warming.

An estimated 14.5 per cent of the planet's [global warming](#) emissions stem from from the keeping and eating of livestock – more than from the entire transport sector.

Livestock emit methane, a potent greenhouse gas, while land clearing and fertilisers release large quantities of carbon.

"Through this kind of lifestyle change, it is expected that the livestock industry will transform and carbon emissions will be reduced," said Li Junfeng, director general of China's National Center on Climate Change Strategy and International Cooperation.

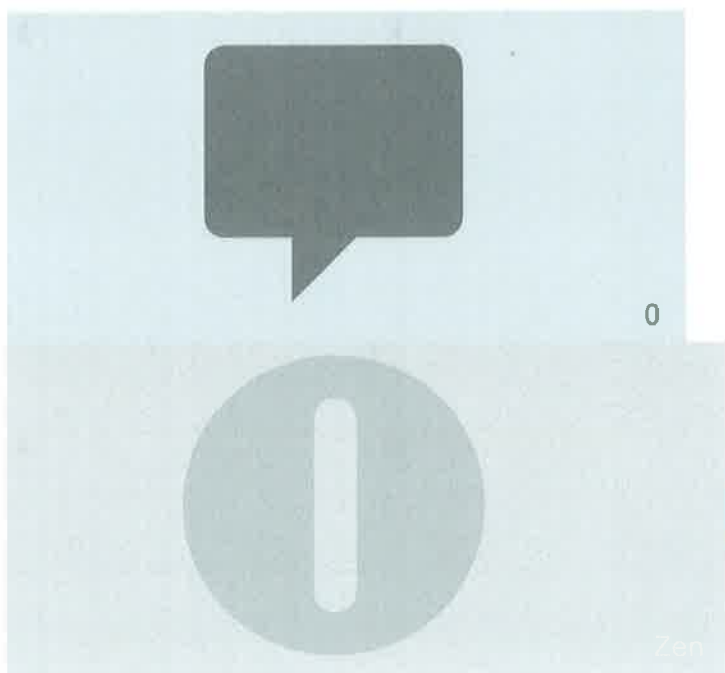
A recent report by scientists at the Oxford Martin School found the widespread adoption of vegetarianism around the world could bring down greenhouse gas emissions by nearly two-thirds. ●

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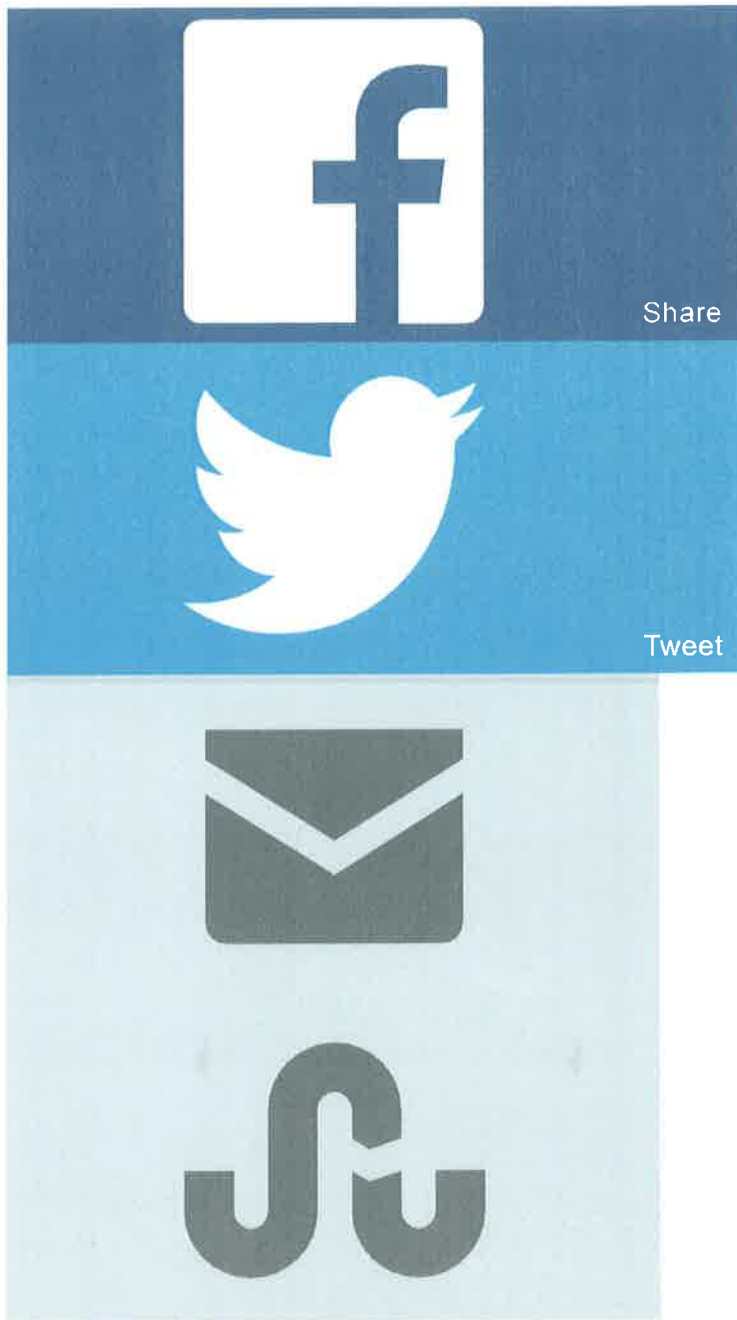
Israeli Institutions Working to Bring Cultured Meat From Lab to Plate

Four years since the first lab hamburger was introduced, the cultured meat field is flourishing in Israel and abroad. Who knows what people will be grilling come next Independence Day

By Ido Efrati Apr 30, 2017



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**Will Israel become the world's first vegan country?
The Impossible Burger: The beginning of the end for
beef?
This Tel Aviv restaurant is amazing - but it's only open
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There is no pleasant way of saying this: At the moment there is nothing appetizing about the future plate of food that awaits humanity. The food of the future will arise from resource shortages, demographic increases and pangs of conscience – not exactly a recipe for gourmet culinary pleasures. The meals that will be served to our offspring and future generations will be laden with nutritional considerations and will consist of sophisticated substitutes for food as we know it.

It's possible this food will be healthier and we might take consolation in the thought that it's all about acquired tastes, but we'd best come to terms with the fact that this is the direction we're heading.

Alongside grasshopper delicacies, cricket tidbits and other six-legged protein, there is also the question of the future of meat for consumption. To the chagrin of its opponents and the abstemious, meat is still the main element in world food consumption. We humans spend about \$750 billion annually on meat, compared to \$330 billion on milk and dairy products and about \$280 billion on fruits and vegetables.

However, ever since the first lab hamburger was introduced to the world four years ago, the idea of cultured" meat has begun to take on sinew and flesh. The idea of producing real meat – not a substitute – from animal cells in the laboratory without harming the animals themselves or causing them to suffer is no longer a fantasy. It is currently being developed in startups and research institutions, arousing interest in the meat industry and among investors and government bureaucrats. The international race to create cultured

possible that when next Independence Day rolls around, we will place juicy lab-grown steaks on the grill, steaks grown without bloodshed and without harming any animals.

Last month Uma Valeti, the founder and CEO of Memphis Meats, announced with great excitement that a year after the company made history by launching its first (cultured) meatball, it did it again by successfully producing chicken and duck.



Chicken nuggets by Memphis Meats. Memphis Meats

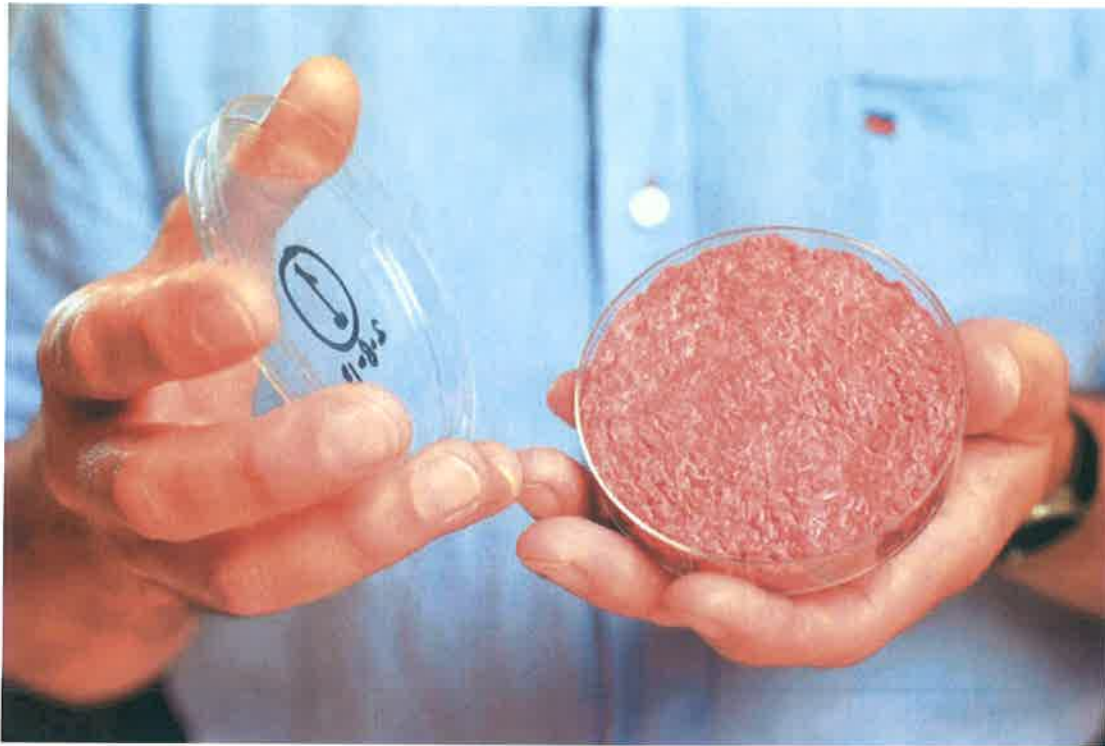
San Francisco-based Memphis Meats is probably the most advanced company in the cultured meat field. However, even if the taste and texture of Valeti's lab schnitzel trounces the local schnitzel joints, it costs over \$18,000 per kilogram. This is far more expensive than the schnitzel we know and love, but significantly less expensive than the first lab hamburger, which debuted in April 2013 at the cost of \$325,000 for a 140-gram patty.

Lab cookout

Israel is also a major player in the field of cultured meat, though nothing is ready for the supermarket shelves yet. On May 7, the Technion - Israel Institute of Technology in Haifa will host the first Israeli international conference on the topic of cultured meat, aptly named Future Meating. The guest of honor will be Prof. Mark Post from Maastricht University in Holland, who presented the first cultured hamburger. Also expected is the chief scientist of Tyson Foods, the second-largest chicken meat supplier in the world which provides its products to chains like McDonalds and Kentucky Fried Chicken. Among the conference's local sponsors are Soglowek Food.

Industries and Strauss Israel, which along with the Innovation Authority at the Economy and Industry Ministry established a food-tech incubator for entrepreneurs in the food industry about two years ago – the Kitchen FoodTech Hub.

The conference was initiated by the Modern Agriculture Foundation, which was established in 2014 with the aim of promoting and supporting research to implement the idea of cultured meat. According to Dr. Yaron Bogin, the executive director of the nonprofit, The field of cultured meat is in its infancy and thus far worldwide investment in it has been at most a few million dollars. What we do, broadly speaking, is that we take a sample of cells from a cow or a hen, put them into bioreactors [the apparatus used for growing cells], add nutrients [chemical compounds essential for the growth of living beings] to them, cause the cells to divide and multiply and then we turn them into muscle cells, harvest them and make meatballs from them. According to him, the problem is that they still haven't come up with the ability to grow cells with all the elements of the tissue.



Professor Mark Post holds the world's first lab-grown beef burger during a launch event in London, August 5, 2013. REUTERS

No prototype of cultured meat exists in Israel as of yet, but they are definitely working on it. With a little faith and luck, Haifa will be able to take pride in cultured steaks produced by the Technion along with its famous Shawarma Hazan meat restaurant.

One of the conference participants is Prof. Shulamit Levenberg, dean of the Technion's biomedical engineering department, where a team of researchers she heads has recently begun to develop cultured meat based on cattle cells. The team doesn't intend to stop at a clump of cell culture formed into a meatball. They are going for the real thing: steak. At the end of the process they intend to produce a succulent lab steak untainted by animal suffering, equal in taste and texture to the genuine article.

We have been working for many years now on creating muscle tissue for medical purposes, for replacing and repairing defects, with an emphasis on complex tissues consisting of a number of types of tissue," says Levenberg, an expert on tissue engineering. "The main challenge is to replace the materials suited for medical applications of tissue engineering with materials suited for food. That is, what is good for repairing defects and injuries in stomach or thigh muscles could one day show up for lunch.



Prof. Shulamit Levenberg. Rami Shlulush

Growing meat in an apple

They have also taken up the challenge at Tel Aviv University. Prof. Amit Gefen of the biomedical engineering department is growing meat cells in apples; he is currently trying to find the variety of apple best suited to the task. He began working in the field after conducting feasibility studies for developing cultured meat for the Modern Agriculture Foundation two years ago. They have parted ways since then, but he opted to continue his academic research. According to Gefen, Experience accumulated abroad shows that it is possible to grow cells from a mammalian source on apples because of the structure of their porosity. The pores are sort of niches that provide the mammalian cells with a protected habitat in which the biological processes necessary for one day becoming a tasty piece of steak can occur.

These attempts show the complexity of meat and how difficult it is to replicate. Taking a cell sample and creating a culture that will make it possible for the cells to do their thing, as it were, is far from sufficient; the whole process requires intervention.

The main difficulty is growing a thick meat tissue – that is, finding a solution to the absence of blood vessels, which carry oxygen and much else to the depths of real meat tissue. This is essential in order to create the texture of real meat and not just a thin layer of meat cells in a lab Petri dish.

Post created the first lab hamburger after experiments with mouse and pig cells. He took stem cells from the muscle tissue of a cow and from them he produced satellite cells that repair damaged tissues. He grew them in a culture rich with growth materials and hormones. After the cells multiplied, Post transferred them to a dish with collagen, which served as an armature and then starved the cells, stimulating a reaction that caused them to become linked muscle cells.

Afterward, another process was needed to create resistance and apply pressure to the meat filaments in order to develop muscles and give them a texture similar to that of animal flesh. Then the flat coverings of muscle cells on the armatures were cut into very thin strips, from which Post made the patty itself. To make the lab hamburger look like the real thing, he added beet juice and spices and sauted it in a considerable amount of butter because it didn't contain any fat cells. The process took about three months. At the end, the patty was served to tasters who said it was close to meat.



Prof. Amit Gefen of Tel Aviv University, April 2017. Tomer Appelbaum

A dish with an agenda

The challenge of transforming a cell culture to real tissue is forcing researchers to focus on the search for a suitable armature (that is, a growth medium). Gefen chose apples as an armature but potatoes, yams and asparagus are also being considered. It isn't enough that the material be porous – the cells need to connect to each other, explains Gefen. We sowed apple cells. For them to be ready to accept the cells, first we needed to treat them. It's a complicated story.

He explained his choice to work with quail meat – as opposed to the popular chicken or beef – by his preference for concentrating on the kinds of cells that have been less studied until now, and because it's used in haute cuisine. These developments are costly, at least in our day," says Gefen. I don't think the cultured meat will be sold to McDonalds or KFC. It will be served with an agenda, and in specific places. It's important to remember that this is in its infancy and we aren't going to be seeing cultured meat in restaurants or shops in the next several years, unless it's for public relations for commercial purposes.

Where's the beef?

The market for alternative-protein products

Plant-based "meat" products have made it onto menus and supermarket shelves



Print edition | Business >

Feb 2nd 2017



MOST people like to eat meat. As they grow richer they eat more of it. For individuals, that is good. Meat is nutritious. In particular, it packs much more protein per kilogram than plants do. But animals have to eat plants to put on weight—so much so that feeding livestock accounts for about a third of harvested grain. Farm animals consume 8% of the world's water supply, too. And they produce around 15% of unnatural greenhouse-gas emissions. More farm animals, then, could mean more environmental trouble.

Some consumers, particularly in the rich West, get this. And that has created a business opportunity. Though unwilling to go the whole hog, as it were, and adopt a vegetarian approach to diet, they are keen on food that looks and tastes as if it has come from farm animals, but hasn't.



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The simplest way to satisfy this demand is to concentrate on substitutes for familiar products. "Meat" made directly from plants, rather than indirectly, via an animal's metabolism, is already on sale for the table and barbecue. Impossible Foods, a Californian firm, has deconstructed hamburgers, to work out what gives them their texture and flavour—and then either

found or grown botanical equivalents to these. It launched its plant-based burger in a number of upmarket restaurants in America last year. Beyond Meat, another

plant-based hopeful, has compounded from legumes something that tastes like chicken. This has been on sale since 2012. Last year, its “beef” patty (pictured) reached the shelves of several stores belonging to the Whole Foods Market chain.

For those who really want to eat steak while saving the planet, a second approach may be more promising. This is “clean”, or cultured, meat—made by taking animal cells and growing them in a factory to form strips of muscle. Steak is not yet on the menu, but burgers and meatballs may soon be. The field leader is Mosa Meat, a Dutch firm staffed by scientists. The first burger it made, in 2013, cost around \$300,000. By 2020, it hopes, the price of making them will have come down to about \$11. Close behind Mosa, Memphis Meats, an American startup, is looking at the meatball rather than the burger market. Between 2013 and 2015 it managed to bring its costs down a hundredfold—though even then a single meatball would have set you back \$1,200.

Milk, too, is in the sights of the new no-animal farmers. Perfect Day, a startup based in Berkeley, California, makes “milk” that has the same nutritional value and taste as traditional, dairy-based sources. It does so by engineering the relevant cattle genes into yeast cells, and growing those in fermentation tanks.

And there is one more novel source of meaty protein that does not involve farm animals—at least, farm animals of the conventional sort. This is insects. Grasshoppers, for example, are around 70% protein. Insects do have to be fed. But, being cold-blooded, they convert more food into body mass than warm-blooded mammals do and, being boneless, more of that body-mass is edible. Per edible gram, they need only a twelfth of the food that cattle require—and even only half as much as pigs.

Here, the problem is marketing. Around 2bn people eat insects already, but few of them are Westerners. Changing that could be a hard sell. Grind the bugs up and use them as ingredients, though, and your customers might find them more palatable. Hargol FoodTech, an Israeli startup, plans to do just that. Locustburgers, anybody?

This article appeared in the Business section of the print edition under the headline "Plant and two veg"